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In re application of: Peter Bennett Duff WHYTE
Serial No.: 09/702,037 Group No.: 1761
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For: Food Composition and Method of Using Same

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Attached please find the certified copy of the foreign application from which priority is claimed for this case:

Country: Australia

Application
Number: PP3271

Filing Date: 30 April 1998

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Janet I. Cord
(type or print name of person certifying)

SIGNATURE OF PRACTITIONER

JANET CORD

(type or print name of practitioner)

Reg. No. 33778

Tel. No.: (212) 708-1935

Customer No.:

P.O. Address

c/o Ladas & Parry LLP
26 West 61st Street
New York, N.Y. 10023

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I, MICHELLE HENKEL, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PP 3271 for a patent by NORTHFILED LABORATORIES PTY. LTD. as filed on 30 April 1998.

WITNESS my hand this
Twenty-fourth day of May 2006

MICHELLE HENKEL
TEAM LEADER EXAMINATION
SUPPORT AND SALES

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AUSTRALIA
Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: A FOOD COMPOSITION AND METHOD OF USING SAME

Applicant: NORTHFIELD LABORATORIES PTY. LTD.

The invention is described in the following statement:

A FOOD COMPOSITION AND METHOD OF USING SAME

The present invention relates to a food composition preferably for changing body composition and/or physical work capacity. The invention further provides a method of improving body composition and/or physical work capacity.

Colostrum is the first milk secreted by the mammary glands at the end of pregnancy. It differs in composition to the milk produced later. Colostrum is a rich source of growth and anti-microbial factors (Donovan, S. M. and Odle, J (1994); Foley, J. A. and Otterby, D. E. (1978); Reiter, B. (1978); Shams, D (1994)). Hyperimmune colostrum is commonly used as a source of antibodies against pathogens and has successfully been used to treat pathogens such as rotavirus. However, colostrum products have also been used to enhance growth of growth retarded children, (Zumkeller, W (1992)) and to stimulate growth of small intestine in newborn piglets (Tungthanathanich, P. R. et al (1992)).

All growth activity cannot be explained by one or other known growth factors alone or in combination. Colostrum is a complex mix of growth factors, and other bioactive substances.

One of the many growth factors found in colostrum is IGF-I. In the bovine colostrum, the concentration is more than 20 times greater than in normal milk (Marcotty, C. F. et al (1991); Oda, S. H. et al (1989); Skaar, T. C. (1991)). Bovine and human IGF-I are very similar in composition.

Like many other growth factors, IGF-I has been shown to have anabolic effects on skeletal muscles (Fryburg, D. A. et al (1995); Tomas, F. M. et al (1991)); and metabolic effects in increasing fat utilisation (Tomas, F.M. et al (1991)). However, the proteins for which IGF-I and other growth factors increase synthesis is unclear and therefore the anabolic and metabolic effects caused by these factors are not clearly understood. Therefore, all growth factor activity in colostrum cannot be explained by IGF-I alone or other known factors.

IGF-I and other growth factors in their pure forms are expensive. Their use is generally confined to specific medical and pharmaceutical indications

including tissue growth and repair. IGF-I and other growth factors are generally regarded as being rapidly denatured in the gut prior to absorption (Xian, 1995). Therefore, the effects of the growth factors such as IGF-I, if denatured, would not be expected to be delivered in an active form to the blood by an oral route.

Animal and human studies have shown that if pure IGF-I is ingested, no more than 6% or 10% may be absorbed intact in the serum (Donovan, S.M. et al, (1994)). Even if up to 10% were to be absorbed, this would only lead to a non-significant increase in human serum IGF levels.

Despite the presence of IGF-I and other growth factors in colostrum, it has not been proven that IGF-I and/or other factors from bovine colostrum are available at an effective dose as anabolic agents in humans, nor has colostrum itself been shown or proven to act in an anabolic manner in humans. Therefore, it is generally considered that colostrum would have no benefits on body composition and/or physical work capacity if ingested by humans.

Medical benefits of IGF-I have been obtained via parental administration of human IGF. A readily obtainable source of growth factors, high in IGF-I or other growth factors which has been found suitable to change body composition and/or physical work capacity or to enhance performance in subjects wishing to obtain an improvement of the body such as athletes or for use by patients in a catabolic state/weight loss or for those experiencing fatigue has not been available, nor has there been a convenient or effective means to improve body composition or physical work capacity.

Accordingly it is an object of the present invention to overcome or at least alleviate some of the problems of the prior art.

In one aspect of the present invention there is provided a food composition for use in changing the body composition and/or physical work capacity, said food composition including colostrum.

The term "physical work capacity" used herein is a measure of the ability to do physical work including any exercise performance, recovery after exercise and reduction of fatigue. The exercise performance may include any one of the exercises selected from the group including (but not limited to) running, walking, jumping, sprinting, knee extensions, knee flexions, squatting, lifting and

kicking.

The term "body composition" used herein includes those parameters used to define the make-up of the body including markers of anthropometric or metabolic change selected from the group including (but not limited to) percentage body fat, fat mass, fat free mass, dietary intake, oxygen uptake (VO_2max), respiratory exchange ratio (RER), blood, serum creatine kinase (CK), lactose: rhamnose ratio (L:Rh) and blood lactate.

The term "changing body composition and/or physical work capacity" as used herein is a change which results in an improvement to the body. An "improvement" may be any change which is favourable for achieving a result. For instance, an improvement for achieving weight loss or body toning may include a reduction in body fat and an increase in fat-free mass (increased lean tissue and increased loss of fat tissue). Preferably the ratio of fat-free mass to body fat is increased. Preferably the change is an improvement of exercise performance to achieve better athleticism or better endurance in occupational circumstances.

The food composition is preferably for use in changing, in a favourable or improved manner, body composition and/or physical work capacity preferably in subjects wishing to obtain an improvement to the body as described above, athletes, people with physically demanding occupations or pastimes, or patients in a catabolic state/weight loss situation, or experiencing fatigue. When the food composition is administered to an athlete, it is considered that the food composition including colostrum and a carrier may have a positive effect on the athlete who is subjected to metabolic and physical stresses which normally lead to anthropometric and metabolic adaptations even without supplementation with the food composition.

The food composition may be used by any type of athlete. The athlete may be a power/strength athlete (PSA) or an endurance athlete (EA). The PSA generally undertakes strength and power training as part of their normal training programme. The EA generally undertakes programmes which enhance their ability to undertake prolonged exercise.

The food composition includes colostrum. The source of colostrum may

be from any mammal selected from the group including the bovine, ovine, porcine, caprine or equine. Preferably, the colostrum is from the bovine. More preferably the colostrum is collected in the first few days after the end of pregnancy, preferably up to 3 or 4 days after the end of pregnancy.

The colostrum may be treated to reduce contaminants. Preferably the colostrum has a bioavailability as close to that of untreated colostrum.

In a preferred aspect of the present invention there is provided a food composition for use in changing body composition and/or physical work capacity, said food composition including colostrum having a mixture of growth factors and a carrier.

Preferably the growth factors are colostrum-derived and may include IGF-I, preferably derived from colostrum. Pasteurisation and some other treatments used to reduce contamination or produce colostrum products can destroy or reduce the levels of growth factors and other bioactive substances including growth factors found in colostrum, and/or reduce their stability/bioavailability in the gut.

IGF-I has anabolic effects which may contribute to increased synthesis of contractile proteins which leads to an increase in muscle mass. This may benefit users in terms of increasing muscular power and strength. Preferably, the food composition is for use in changing the exercise performance or physical work capacity in PSA.

However, the only study to date by Mero, A. et al (1996) which has investigated the effect of an orally administered bovine colostrum whey extract on muscular power failed to find any positive effect. Lower IGF-I levels may account for the absence of effect. Also the lack of casein proteins and manufacturing processes could lead to less IGF-I and other factors in the processed colostrum. Casein has been shown to contribute to enhancement of bioavailability of IGF-I at conditions found in the gut (Xian, 1995). Also the daily dose given and duration of supplementation (ie. the method of using the composition) may have been deficient.

Accordingly, the present invention also includes a food composition for use in change in the body composition and/or physical work capacity, said food

composition including colostrum casein. Preferably the casein is colostrum derived and has been retained in the colostrum following processing of the colostrum.

Metabolic effects of IGF-I show that it increases fat utilisation. It is possible that EA in particular will benefit from this by increasing physical work capacity by having a greater ability to utilise fats for energy during exercise. Increased utilisation of fats may lead to increased glycogen sparing and less lactate accumulation, both of which are associated with a reduction in fatigue and improved performance. Therefore, it is preferable that the food composition is for use in changing the exercise performance or physical work capacity for a EA.

Preferably the concentrations of anabolic growth factors such as IGF-I are at least the concentrations found in normal untreated colostrum. However, they may be higher. Preferably the growth factors will be in a composition that maximise their availability in the gut.

The food composition may also serve as a means of increasing growth factors such as IGF-I levels in the body. IGF-I and other factors in the colostrum have been implicated in growth and repair. Their anabolic and metabolic effects may also effect the body composition and physical work capacity. However, if the growth factors are destroyed by digestion in the gut after oral administration, the interplay of factors in colostrum may be unable to contribute to the improved changes in body composition and/or physical work capacity.

The food composition may be supplemented by a carrier. The carrier may support the delivery of the colostrum to the subject as described above. The carrier may be any liquid, solid or semi-solid carrier. It may be a carrier selected from the groups including full cream, skim, modified, flavoured milk, yoghurt including natural, flavoured, frozen or drinking yoghurt, tonics, and sports drinks, other dairy products such as custards, cheese and cottage cheese formulations and ice creams. Semi-solid carriers may be selected from pastes and spreads. Solid carriers may include food bars, biscuits, cereals, food fibres.

The food composition may include other supplements beneficial for changing the body composition and/or physical work capacity.

Supplements may be selected from the group including other proteins which may not be found in colostrum, minerals and electrolytes, salts, proteins, amino acids, (branched and unbranched), nutrients, lipids, fats, vitamins, carbohydrates (simple and complex), inosine, creatine and other factors which supplement the diet during training.

Preferably, the minerals may be selected from the group including calcium, iron, phosphorus, iodine, magnesium, zinc, copper, chromium, molybdenum, and magnesium.

Preferably, the vitamins may be selected from the group including ascorbic acid (vitamin C), D-Alpha Tocopherol (vitamin E), Niacin (vitamin B3) Riboflavin (vitamin B2), Pantothenic Acid (vitamin B5), Pyridoxine HCl (vitamin B6), Thiamine (vitamin B1), Folic Acid, Cyanocobalamin (vitamin B12), and Cholecalciferol (vitamin D3).

Preferably, the amino acids are selected from the group including Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Threonine, Tryptophan, Valine, Alanine, Arginine, Aspartic Acid, Cystine, Glutamic Acid, Glycine, Proline, Serine and Tyrosine.

Preferably the nutrients are selected from the group including Biotin, PABA, Choline, Inositol, L-Carnitine, Betaine, and Gamma Oryzanol.

Preferably the salts are selected from the group including sodium, potassium, and magnesium.

Preferably the carbohydrates are selected from the group including sucrose, maltodextrose, glucose and fructose.

Preferably the fats are selected from the group containing fat milk solids and vegetable fat.

Preferably other factors are selected from the group including emulsifiers such as lecithin, food acids, flavours, preservatives and colourings preferably to improve the delivery and preservation of the food composition.

The food composition may also be provided in any form including a powder, liquid, semi-solid or solid. The food composition may also be delivered

as a unit dosage form such as in a tablet, capsule or powder.

In another aspect of the present invention there is provided a method of preparing a food composition including colostrum having growth factors for use in changing body composition and/or physical work capacity, said method including:

providing colostrum prepared by a process including:

subjecting colostrum to an ultra-filtration process to provide an ultra-filtered colostrum retentate;

subjecting the ultra-filtered colostrum retentate to a spray drying process, providing the colostrum is not treated to remove or separate casein; and

removing the spray-dried colostrum.

The colostrum may be further subjected to a bacterial reduction step preferably utilising centrifugation. The centrifugation may be a flow through centrifugation wherein the centrifugation is performed by controlling throughput and thereby residence time of the colostrum during centrifugation.

Pasteurisation and some other treatments used to reduce contamination or produce colostrum products can destroy or reduce the levels of growth factors and other important bioactive constituents including growth factors and other factors found in colostrum and/or reduce their stability and bioavailability in the gut. Those other factors and constituents may include immunoglobulins, lactoferrin, lactoperoxidase, lysozyme, oligosaccharides etc.

Accordingly, it is preferable that the colostrum is treated by any process to preserve or to enhance the levels of growth factors and other bioactive proteins or carbohydrates contained therein. Preferably, the colostrum is processed according to the processes outlined in patents AU668033, AU644468, NZ239466, NZ260568 or PCT/AU96/00708, the contents of which are referred to and incorporated herein.

These processes of treating colostrum may further remove salt and contaminants such as bacteria and somatic cells from the colostrum whilst maintaining the bioavailability as close to that of untreated colostrum preferably including casein in the product. Casein has been shown to enhance the

bioavailability of IGF-I at conditions found in the gut lumen. The colostrum may be prepared by the following process:

a) the colostrum from up to the first 6 milkings following calving is collected;

b) the colostrum is warmed to 55°C and skimmed in a standard dairy separator to reduce fat;

c) the skimmed colostrum is then pasteurised at 63°C for 30 minutes and/or centrifuged at 12,000 g in a bactofuge to reduce bioburden and preferably to also improve ability to process downstream;

d) the pasteurised skimmed centrifuged colostrum is then either added to fresh dairy products ready for consumption with said dairy products acting as a carrier or ultra-filtered to reduce water, lactose and electrolyte levels in order to concentrate the protein content; and

e) the concentrate is then either added to fresh dairy products ready for consumption said dairy products acting as a carrier, or spray dried or processed in a manner such as ion exchange chromatography, filtration or UHT, to obtain a long life liquid (LLL) retaining activity of growth factor proteins.

The spray dried powder or LLL can be included in food or pharmaceutical products or taken as is, or reconstituted by the consumer with any suitable carrier.

Preferably the colostrum maintains levels and bioactivity of growth factors similar to that of unprocessed colostrum. The bioactivity can be measured using cell growth assays and making the comparison to untreated colostrum. This may be achieved by utilising the processes outlined in AU668033, AU644468, NZ239466, NZ260568 or PCT/AU96/00708, the contents of which are referred to and incorporated herein. Those processes also maximise the bioavailability of the IGF-I by the retention of casein.

In another aspect of the present invention, there is provided a method of changing body composition and/or physical work capacity, said method including administering an effective amount of a food composition including colostrum and a carrier.

Preferably, the food composition is as described above.

The food composition is preferably for use in changing, in a favourable or

improved manner, body composition and/or physical work capacity preferably in subjects wishing to obtain an improvement to the body as described above, athletes, people with physically demanding occupations or pastimes, or patients in a catabolic state/weight loss situation, or experiencing fatigue.

There is also provided a method of increasing tissue mass, said method including administering an effective amount of food composition including colostrum and a carrier.

The tissue may be a tissue selected from the group including adipose, connective, muscular or nervous tissue. The tissue may be gut tissue or other tissue.

The body composition may change by increasing gut or other tissue mass via an increased synthesis of contractile protein. The anabolic effects of growth factors such as IGF-I present in colostrum may lead to these increases if provided in a manner which maximises bioavailability of these factors in the gut. A changing of physical work capacity may result from the increased muscular power and strength. Preferably the method is for a PSA.

Also provided is a method of increasing fat utilisation, said method including administering an effective amount of a food composition including colostrum and a carrier.

An increased muscle mass and increased fat utilisation may result in a changing of body composition which includes an increased lean body mass through increased synthesis of proteins due to the anabolic effects of IGF-I and/or other colostrum factors. Preferably there is reduced fat mass through increased utilisation of fatty acids due to stimulation of fat metabolism by IGF-I and/or other factors. However, an increased metabolic rate may also result from an increased fat-free mass (FFM). This is particularly helpful for the PSA but also for those wishing to improve their body by weight loss.

There is also provided a method of reducing fatigue, said method including administering an effective amount of food composition including colostrum and a carrier.

A reduction in fatigue may contribute to a change in physical work capacity experienced through increased muscle mass, or possibly through

increased fat metabolism and increased glycogen sparing resulting in less lactate accumulation.

Preferably, the method is for use by a EA.

Also provided is a method of increasing recovery after exercise said method including administering an effective amount of a food composition including colostrum and a carrier. The increased recovery may manifest as an improvement in performance.

There is also provided a method of increasing growth factor and/or other colostrum component levels in the body, said method including administering an effective amount of food composition including colostrum and a carrier.

The increased growth factor or other colostrum component levels may result in a change to the body composition and/or work capacity.

Preferably, the increased growth factor component levels are provided by the colostrum (colostrum-derived). Increases in growth factors in particular may contribute to any of the changes in body composition and/or physical work capacity mentioned herein. Preferably, the growth factor is IGF-I.

The levels of IGF-I may increase in the body, preferably in the gut. Levels of IGF-I in the blood have generally been shown not to increase significantly after oral administration. However, maximum bioavailability is achieved by the composition herein described, which has overcome some of the problems of obtaining improved work capacity/body composition.

Accordingly, there is provided a method of treating or preventing a disorder of the gut, said method including administering an effective amount of a food composition including colostrum and a carrier.

A disorder of the gut may be selected from the group including mucositis, gastrointestinal damage from administration of non-steroidal anti-inflammatory drugs, gastrointestinal damage from irradiation therapy, gastrointestinal damage from chemotherapy, damage from infection caused by pathogens (rotavirus, *E. Coli spp, Salmonella spp, Cryptosporidium spp, H. pylori* etc), eg in HIV/AIDS patients, and damage from gut surgery.

The colostrum may be hyperimmune colostrum from animals vaccinated in order to produce antibodies effective in preventing or treating infectious

diseases. Athletes undergoing heavy training programmes are at risk of infections due to lowered immune status and by often travelling.

Endurance athletes sometimes suffer bouts of diarrhoea which are induced by their training. Damage to the intestinal mucosa is known to increase intestinal permeability and cause diarrhoea [Ford, R.P.K. et al (1986)] and although the precise mechanism of the diarrhoea experienced by endurance athletes is unknown, it is generally accepted that mechanically induced damage to the intestinal mucosa resulting from repetitive compression of the gut during long training sessions increases intestinal permeability and leads to episodes of diarrhoea.

There is also provided a method of reducing muscle damage during exercise, said method including administering an effective amount of a food composition including colostrum and a carrier.

Creatine kinase is present in skeletal muscle, brain tissue and heart tissue and damage to these tissues results in the release of increased levels of creatine kinase into the blood. Plasma creatine kinase concentrations are sometimes elevated during exercise, indicating that the exercise has induced muscle damage. The increased IGF-I and/or other factors provided in colostrum may contribute to an increase in protein structure of muscle and thereby preventing against injury, or may improve wound repair, thereby contributing to the reduced muscle damage during exercise.

In a preferred aspect there is provided a method of changing body composition and/or physical work capacity said method including administering over an effective period an effective amount of a food composition including colostrum and a carrier.

Preferably, the food composition is as described above and prepared by the methods outlined above.

The term "effective period" is a period wherein a significant improvement in body composition and/or physical work capacity is noticed. Preferably, the period is up to 4 weeks. More preferably the period is up to 8 weeks.

The term "effective amount" will depend on the subject undergoing the improvement and on the bioactivity of the factors in colostrum, and on the

bioavailability of those factors in the gut. Preferably, the subject is a PSA or a EA. The level of colostrum may be determined by the equivalent amount of IGF-I present in the colostrum. Preferably, the dose is equivalent to 0.05 to 0.5 mg of IGF-I per day. However, for colostrum preferably prepared as described herein, the daily dosage may equate to approximately 5 to 100 g per day. Casein has been shown to be very effective for preserving IGF-I in the gut. Where casein is absent, the equivalent amount of IGF-I required for an effective amount may be at least as much as 4 to 5 times the dose.

In determining the dosage of colostrum powder, consideration should also be given to the quantity of colostrum powder that could reasonably be consumed for a day. The colostrum powder may be dissolved in any carrier of liquid, semi-solid or powder form as described above. Skimmed milk or a skimmed milk/water mix may be used so that it can be taken orally as a food drink. 40 gms of bovine colostrum powder can be adequately dissolved in 250 ml of skimmed milk/water. It is preferable that the subjects be given a dosage of approximately 5 to 100 gms per day. More preferably, the subject is given 60 gms of colostrum per day. Preferably the colostrum has been prepared by the above mentioned processes, preferably for retaining casein in the colostrum.

The colostrum may be delivered to the subject in a single dose or in multiple doses over a period of 24 hours providing the total dosage is delivered over the 24 hour period. For example, for a 60 gm dosage of colostrum, 20 gms of bovine colostrum powder may be provided to the subject in morning and 40 gms of bovine colostrum powder may be provided in the evening.

In a further preferred aspect there is provided a method of changing body composition and/or physical work capacity in an athlete, said method including administering to an athlete an effective amount of a food composition including colostrum and a carrier.

Preferably the colostrum is prepared as described herein.

Preferably, the athlete is a PSA or an EA. The two types of athletes have different demands on their training which leads to differences in the way their bodies adapt.

The changed body composition may be a change measurable by comparing anthropometric measurements over a period of time, preferably over a period of at least 4 weeks, more preferably over 8 weeks. Preferably, the anthropometric measurements are selected from the group including height, mass, skinfolds, thigh girths, calf girths, leg volumes, and body composition by hydrodensitometry. Therefore it is preferred that the method is applicable to changing any one of these anthropometric measurements.

The changed physical work capacity may be measured by comparing an athletes performance of a battery of exercises over a period of time, preferably over a period of at least 4 weeks, more preferably, over 8 weeks. Preferably, for a PSA, the battery of exercises may be selected from the group including measuring the effect on a cycle, knee extensions, and/or knee flexions, vertical jump heights and sprint accelerations. Preferably, for an EA, the test battery may be selected from the group including but not limited to measurement of a treadmill lactate threshold test to determine total distances covered to exhaustion, total work done, peak oxygen uptakes, oxygen uptake and heart rates at lactate threshold and respiratory exchange ratios (RER) and blood lactate concentrations during submaximal exercise.

Therefore, it is preferred that the method is applicable to changing any one of these measurements. Most preferably there is provided a method of improving running performance in an EA, said method including administering over an effective period, an effective amount of a food composition including colostrum and a carrier.

Preferably, the colostrum is prepared as described herein.

Also it is preferable to provide a method of reducing serum creatine kinase (CK) levels in PSA or an EA, said method including administering over an effective period, an effective amount of a food composition including colostrum and a carrier.

Preferably the colostrum is prepared as described herein.

The reduced levels of serum CK may be a result of reduced muscle damage. Accordingly, there is also provided a method of reducing muscle damage by administering to an athlete an effective amount of a food

composition including colostrum and a carrier.

Administration may be via any route which does not cause side effects to the body. For instance, colostrum contains high levels of proteins which may cause immune responses. Therefore, injection is not a suitable means of administration. However, other means including oral, rectal, or dermal administration is suitable providing sufficient colostrum can be delivered to the body.

Administration may be staggered or continuous. By "staggered", it is meant that a dose could be delivered at intervals during the day. By "continuous" the colostrum may be delivered to the body via a pump or other continuous delivery means either to the mouth or directly to the gastrointestinal tract.

During a period of training the food composition including colostrum and a carrier may be administered before and/or during exercise. If administered before, the colostrum may act in preventing damage. If administered during exercise, the food composition may act to reduce or treat damage caused during exercise.

Colostrum may be administered after exercise to treat damage caused by exercise. If hyperimmune colostrum is used, administration before and during exercise could help prevent infection. If administered after, the colostrum could help treat infection and gut damage by combined activity of antibody and growth factors.

The present invention will now be more fully described with reference to the following examples. It should be understood, however, that the description following is illustrative only and should not be taken in any way as a restriction on the generality of the invention described above.

IN THE FIGURES:

Figure 1 illustrates the change in percentage body fat in a subject undertaking an endurance training program.

Figure 2 illustrates the change in fat mass in a subject undertaking an endurance training program.

Figure 3 illustrates the change in fat-free mass in a subject undertaking

an endurance training program.

Figure 4 illustrates the oxygen uptake at the lactate threshold in a subject undertaking an endurance training program.

Figure 5 illustrates the change in distance covered in the first treadmill run in a subject undertaking an endurance training program.

Figure 6 illustrates the change in work done during the first treadmill run in a subject undertaking an endurance training program.

Figure 7 illustrates the change in the distance covered during the second treadmill run in a subject undertaking an endurance training program.

Figure 8 illustrates the change in the work done during the second treadmill run in a subject undertaking an endurance training program.

Figure 9 illustrates the change in the distance covered during the second treadmill run as a percentage of the distance covered during the first treadmill run in a subject undertaking an endurance training program.

Figure 10 illustrates the change in the work done during the second treadmill run as a percentage of the work done during the first treadmill run in a subject undertaking an endurance training program.

Figure 11 illustrates the change in the distance covered during both treadmill runs in a subject undertaking an endurance training program.

Figure 12 illustrates the change in the total work done during both treadmill runs in a subject undertaking an endurance training program.

Figure 13 illustrates the change in plasma insulin-like growth factor 1 concentrations in a subject undertaking an endurance training program.

Figure 14 illustrates the change in the serum creatine kinase increase per unit work done in both runs in a subject undertaking an endurance training program.

Figure 15 illustrates the change in the lactulose:rhamnose ratio during the 8 week study period in a subject undertaking an endurance training program.

Figure 16 illustrates the change in the lactulose:mannitol ratio during the 8 week study period in a subject undertaking an endurance training program.

Figure 17 illustrates the change in percentage body fat in a subject

undertaking a power training program.

Figure 18 illustrates the change in fat mass in a subject undertaking a power training program.

Figure 19 illustrates the change in fat-free mass in a subject undertaking a power training program.

Figure 20 illustrates 20 m sprint times in a subject undertaking a power training program.

Figure 21 illustrates the change in best 20 m sprint times in a subject undertaking a power training program.

Figure 22 illustrates the alactic anaerobic power outputs (W/kg) in a subject undertaking a power training program.

Figure 23 illustrates the change in highest alactic power outputs in a subject undertaking a power training program.

Figure 24 illustrates alactic anaerobic work outputs (J/kg) in a subject undertaking a power training program.

Figure 25 illustrates the change in best alactic work outputs in a subject undertaking a power training program.

Figure 26 illustrates vertical jump displacement (cm) in a subject undertaking a power training program.

Figure 27 illustrates the change in best vertical jump displacement (cm) in a subject undertaking a power training program in a subject undertaking a power training program.

Figure 28 illustrates the change in sum of knee extension peak torques in a subject undertaking a power training program.

Figure 29 illustrates the change in sum of knee flexion peak torques in a subject undertaking a power training program.

Figure 30 illustrates plasma insulin-like growth factor 1 concentrations in a subject undertaking a power training program.

Figure 31 illustrates the change in the serum creatine kinase in a subject undertaking a power training program.

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EXAMPLE 1

The Effects of oral colostrum supplementation on body composition and physical work capacity in subjects undertaking a power training program and an endurance training program

The following study was conducted to determine whether bovine colostrum has favourable effects on body composition and physical work capacity. For the present study, bovine colostrum powder was used as a supplement in the food composition. More specifically the study was to determine the effect of oral supplementation with bovine colostrum powder on plasma IGF-I levels, plasma creatine kinase levels after exercise, body composition, physical work capacity and recovery.

The aims were to study whether there are (a) increases in physical power, (2) enhancements of the development of fat free mass and the loss of body fat, (3) reductions in muscle damage during exercise and (4) reductions in intestinal damage in endurance athletes.

MATERIALS AND METHODS

1. Duration of the Study

A period of 8 weeks of supplementation has been chosen for the present study. The 8 week period allows for:

1. Sufficient time for an effect to be observed; and
2. A drop out rate (particularly in a study where the participants will have to depart from their normal "training programmes").

2. Dosage Selection

The present subjects are given a dosage of 60 gms of colostrum per day. This dosage will be provided by consuming 20 gms of bovine colostrum powder mixed with 125 gms skimmed milk/water in the morning and 40 gms of bovine colostrum powder mixed with 250 gms skimmed milk/water in the evening.

3. Subject Selection

Two groups of different athlete populations have been chosen as subjects for the present study, one group consisting of power/strength athletes (PSA) and the other of endurance athletes (EA). These two different groups have been chosen because the differing demands of their training lead to differences in the way in which their bodies adapt. Using two different subject populations will better allow for any specific effect of colostrum supplementation to be isolated.

Moderately well trained athletes were chosen and should have been training for a minimum of 3 months prior to commencement in the study. This minimum 3 months training period was necessary to overcome the problem of neural adaptations (which are predominantly responsible for performance improvements which occur during the first six weeks of training), contributing to large variations in performance improvements within each group (large variability within groups makes it more difficult to demonstrate a statistical difference between groups).

Male subjects have been used in this study.

3.1 Power/Strength Athletes (PSA)

The PSA should be undertaking strength and power training as part of their normal training programme and therefore be reasonably well adapted to this type of training without being specifically adapted to the exercise which will constitute the test battery for the study. Since the participants are already familiar with strength/power training methods, the time required for them to learn the exercises required for the study should be reduced, and they should be able to move straight into a high intensity training programme with little risk of injury.

3.2 Endurance Athletes (EA)

The EA should have been training for at least 3 months. As with the PSA, being reasonably well trained already, they can go straight into a high intensity training programme with little risk of injury.

4. Methodology

4.1 Basic Design

There were two groups involved in the study, 20 PSA and 20 EA.

The study used a single-centre, double-blind, parallel, randomised design.

Each of the two groups have been randomised to one of the following sub-groups:

Sub-Group A: Volunteers receiving 60 g of colostrum, orally, daily for 8 weeks, i.e. 20 g in the morning and 40 g in the evening.

Sub-Group B: Volunteers receiving 60 g of whey protein powder, orally, daily for 8 weeks, i.e. 20 g in the morning and 40 g in the evening.

Subjects have been instructed to eat according to the 12345+ Food and Nutrition Plan (CSIRO Division of Human Nutrition and Anti-Cancer Foundation of South Australia (1991)) for the duration of the protocol and were required to keep a food diary. The food diary was assessed midway through the study to ensure that athletes were keeping accurate records of food intake and training, and were collected at the end of the study for analysis of total energy consumption, daily intake of macronutrients (carbohydrate, fat and protein). All dietary analysis was carried out using the SERVE Dietary Analysis Software program (M. & H. Williams Pty. Ltd.).

Subjects were required to keep a training diary for the duration of the study.

Following an habituation session, where the athletes were familiarised with all aspects of the training and testing procedures the study commenced.

4.2 Testing Procedures

During each of the 3 testing sessions (Trials 1-3) the following anthropometric, physiological and exercise parameters were tested in the order presented below:

4.2.1 Body Mass and Stature (height)

Body mass was measured using a set of electronic digital scales (AND Mercury, FV-150). Stature was assessed using a stadiometer (SECA).

4.2.2 Resting Blood Pressure (RBP)

RBP was monitored with subjects in a seated position using a manual sphygmomanometer (Accoson MK 2).

4.2.3 Thigh and Calf Girths

Thigh and calf girths were measured using a metal tape (Lufkin, W606PM) with subjects standing in the anatomical position. Thigh girths were measured at the midpoint between the greater trochanter and the tibial plateau. Calf girths were measured at the point of greatest circumference.

4.2.4 Fat Mass (FM) and Fat-Free Mass (FFM)

FM and FFM were determined by calculating body density (BD) using hydrodensitometry (underwater weighing) according to the following method:

A chair was suspended by a pulley system from a Western Load Cell connected to a linear chart recorder (Rikadenki). The load cell was calibrated using a 5 kg calibration mass. A minimum of 5 underwater trials were conducted at residual volume and the largest value recorded was taken to be the underwater mass. Water temperature was maintained in the range 30.2° - 36.1° C.

The residual volume was measured by helium dilution using a 10 litre Stead-Wells modular spirometer and helium analyser; 125 ml was subtracted from the functional residual capacity in order to correct for the deadspace of the mouthpiece and the volume of helium absorbed by the blood. The residual volume was measured after the underwater trials. Measurements were recorded whilst the subjects was immersed to neck level and in the same posture as during the underwater trials. BD was then determined from the formula of Goldman and Buskirk (7), except that no correction was applied for gas in the gastrointestinal tract; percentage body fat (%BF) was then calculated according to Siri (18).

There was no significant change in residual volume in either group of subjects throughout the duration of the study ($P>0.05$) so the lowest residual volume recorded for each subject was used for the calculation of BD, %BF, FM and FFM.

The coefficient of variation for the determination of BD using the above method was 0.02%.

4.2.5 Blood Sampling Techniques

After being underwater weighed the subjects dried themselves and changed into their exercise clothing. A venous blood sample (10 ml) was then taken from the median cubital vein at the elbow of one arm. 6 ml of blood was placed into a plastic tube and allowed to clot in order to obtain serum. The remaining 4 ml was placed into a tube containing

dipotassium EDTA as an anticoagulant to obtain plasma. Both tubes were then centrifuged for 10 min at a relative centrifugal force of 2000 *g* at 4° C in a refrigerated centrifuge (Beckman, GS-6R). The serum was then drawn off and divided evenly amongst 3 plastic test tubes and frozen at -20° C for subsequent analysis of serum creatine kinase (CK) concentrations in triplicate (see below). The plasma was drawn off and 1 ml was frozen at -20° C for subsequent analysis of plasma IGF-I concentrations (see below), whilst the remainder was frozen at -20° C in a plastic test tube and retained in case subsequent analysis proved necessary.

The same blood sampling procedure was carried out after each subject had completed the exercise tests, with the exception that all of the plasma was frozen at -20° C in case subsequent analysis proved necessary. No post-exercise plasma IGF-I concentrations were measured.

4.2.6 Determination of Plasma IGF-I Concentrations

Plasma IGF-I concentrations were measured by Dr. P.C. Owens from the Department of Obstetrics and Gynaecology at the University of Adelaide. The plasma concentrations of IGF-I in each sample were measured three times by radioimmunoassay after separation of their binding proteins by high performance size exclusion liquid chromatography at pH 2.5 according to the method of Scott and Baxter (1986) as modified by Owens et. al. 1990; 1994. The mean of the three assays of each sample was taken as the plasma concentration.

This procedure provided an average within-assay coefficient of variation of 10% and a between assay coefficient of variation of 16%.

4.2.7 Determination of Serum Creatine Kinase Concentrations

Serum creatine kinase concentrations were measured by the Diagnostic Services Laboratory of the South Australian Institute of Medical and Veterinary Science. The serum concentrations were measured in triplicate with an Hitachi 917 automatic analyser using a zero order kinetic assay. The mean of the triplicate assays was taken as

the serum concentration.

The coefficient of variation for this assay was 2.4% at 172 U/L and 1.2% at 485 U/L

4.3 Exercise Tests

Each subject performed a battery of four exercise tests. The best of three efforts was recorded as the measured value for each exercise. After completing all four exercises of the test battery each subject was allowed a 20 minute recovery period before the test battery was performed for a second time.

The four exercises which made up the test battery are described below. The exercises were performed in the order presented.

4.3.1 20 m Sprint

Sprint times over a 20 m distance were recorded using a Speedlight Sports Testing System (Swift Performance Equipment). The sprints were all conducted in an indoor sports stadium. Subjects commenced from a standing start at a mark positioned 1 metre behind the first timing light. The Speedlight system began to record the time taken for the sprint when the first light beam was broken and recorded the final time when the light beam was broken at the end of the 20 m running track. Subjects were allowed a two minute recovery between each of three attempts. The fastest time of the three attempts was recorded as the measured value.

4.3.2 Alactic Anaerobic Power and Capacity

The peak power output and total work done during a 10 second maximal cycling test was recorded using a front-access cycle ergometer (Repco) connected to a Work Monitor Unit (Exertech) which recorded the peak power output and the work done. The subjects feet were secured to the cycle pedals using toe-clips and binding straps, and they were then allowed a 2 minute warm up period. Subjects then stood up on the cycle pedals in the ready position. They were then given a countdown (from 3) before performing an all out effort for 10 seconds. Subjects were allowed a two minute recovery between each of three attempts and the

highest peak power output and greatest total work done out of the three attempts were recorded as the measured values.

4.3.3 Vertical Jump

Vertical jump displacement was measured using a height adjustable chalkboard. Subjects chalked the fingers of their preferred hand and stood on their toes, reaching up as high as they could to touch the chalkboard, leaving a chalk mark where their fingers had been. They next performed a counter-movement jump and touched as high as they could on the chalkboard. The vertical jump displacement was the distance between the first and second chalk marks. Subjects were allowed a two minute recovery between each of three attempts and the greatest displacement was recorded as the measured value.

4.3.4 Knee Extension and Flexion Peak Torques

Peak torques generated during 3 consecutive concentric knee extensions and flexions at a movement velocity of 30°/sec were measured using a Cybex II isokinetic dynamometer (Lumex). Each subject was seated in the starting position and their right leg was strapped into the dynamometer before they performed a two minute warm-up. Subjects were then counted down (from 3) and performed 3 consecutive maximal concentric knee extensions and flexions. The highest of the three torques for both the knee flexors and the knee extensors were recorded as the measured values. The same procedure was then repeated for the left leg.

After each subject had completed all four exercises in the test battery they were given a 20 minute recovery before repeating the tests a second time. After the test battery had been completed for the second time the final blood sample was taken. Each subject then had their one repetition maximum (1RM) determined for the following weight lifting exercises:

1. Bench press
2. Chin ups
3. Parrallel dips
4. Biceps curls
5. Leg Press
6. Knee extension
7. Leg curls
8. Calf raises

The 1RM values for these exercises were used to set training weights for the resistance training component of the 8 week training program.

4.3.5 Treadmill Running Tests

The endurance capacity of each subject was determined by having them perform two incremental running tests to exhaustion on a treadmill (quinton Instruments). Each of the two runs was separated by a 20 minute recovery period. The runs were conducted according to the following protocol:

After an initial 3 minute rest period when baseline data were collected, subjects began running at a speed of 10 kmh and 0% grade. The treadmill speed was kept constant at 10 kmh throughout the test and the work load was incremented every 3 minutes by increasing the slope of the treadmill by 1% grade. The slope continued to be increased until the subject reached exhaustion. A 20 minute recovery period was then allowed before the same procedure was repeated a second time.

Heart rate (HR) was recorded continuously during both running tests as 5 second averages with a Sport Tester PE 3000 heart rate microcomputer (Polar Electro) and chest transmitter.

Blood lactate concentrations were measured at the end of the initial 3 minute rest period, at the end of each 3 minute work period, and immediately upon the cessation of exercise using blood collected from a fingertip puncture and an automated lactate analyser (Yellow Springs international, Model 1500 Sport).

Measurements of oxygen uptake and carbon dioxide production were made every 30 sec for both treadmill runs. Expired air was collected into a 2.6 L mixing chamber (Sportech A.C.T) via a 2700 series

Rudolph valve (Hans Rudolph). Ventilatory volumes were measured using a Morgan (Mark 2) ventilation meter and gas fractions were analysed using an Ametak (S-3A/I) oxygen analyser and an Ametek (CD-3A) carbon dioxide analyser. The electrical outputs from the ventilation meter and gas analysers were integrated using an Apple® personal computer which calculated the necessary ventilatory variables.

Oxygen uptake and the blood lactate concentrations from the first treadmill run were used to calculate oxygen uptake at the lactate threshold using a log-log transformation (2). Linear regression analysis was then used to determine the relationship between heart rate and oxygen uptake so that the heart rate corresponding to the oxygen uptake at the lactate threshold was determined. This heart rate was then used as a training heart rate for each subject.

The total work done during each treadmill run was calculated as the product of the vertical distance covered during the run and the gravitational force of the runner (i.e. body mass x 9.81 m/s^2).

After each subject had completed both treadmill runs the final blood sample was taken. Each subject then had their one repetition maximum (1RM) determined for the following weight lifting exercises:

Bench press

Seated rowing

Biceps curls

The 1RM values for these exercises were used to set training weights for the resistance training component of the 8 week training program.

4.4 Training Programs

The training programs were structured as follows, and at least one training session per week was monitored to ensure compliance. At the first weight training session after performance of test battery on day 31, 1 RM was reassessed for all lifts and training weights adjusted accordingly;

4.4.1 Running program for endurance athletes:

Performed 3 times per week with days rest between (eg Mon, Wed, Fri or Tues, Thurs, Sat)

	Exercises
Warm-up	
	5 min slow jogging
	Stretching
Training exercises	45 min continuous running @ HR corresponding to lactate threshold
Warm-down	5 min slow jogging
	Stretching

The heart rate corresponding to the lactate threshold, which was used in the above training program, was determined during the first exercise testing session.

4.4.2 Weight training program for endurance athletes:

Performed 3 times per week on alternate days to running program.

Body part	Exercise	WORKOUT 2 Sets (x reps)	WORKOUT 2 Resistance
Warm-up	5 min slow jog		
	Stretching		
Upper body	Bench press	3 x 20 (or failure)	35% 1 RM
	Seated rowing	3 x 20 (or failure)	35% 1 RM (fast)
	Biceps curls	3 x 20 (or failure)	35% 1 RM (fast)
Abdominals	Incline sit ups	3 x 20	Incline required to cause failure at 20 repetitions

			in final set
	Bent knee raises	3 x 20	Weight of own legs
	Twisting incline sit ups	3 x 10 (each side)	Incline required to cause failure at in final set
Lower back	Back extensions	3 x 20	Own body weight
Warm-down	5 min slow jog		
	Stretching		

After 4 weeks of training all of the testing was repeated and a new training heart rate and new training weights were determined for the final 4 weeks of the study.

Each subject was required to keep a training diary in which records of training completed and any comments of relevance were recorded (e.g. muscle soreness).

4.4.3 Running program for power/strength athletes:

Performed 3 times per week with days rest between (eg Mon, Wed, Fri or Tues, Thurs, Sat).

	Exercises
Warm-up (for all sessions)	Easy jogging (800 m)
	Stretching
	100 m run throughs x 3 (70%, 80%, 90%)
Daily training program	2 x 20 m hopping each leg (full recovery)
	2 x 50 bounding (full recovery)
	10 x vertical jumps (full recovery)

	3 x 20 m sprints (100%) (1 min recovery)
	3 x 50 m sprints (100%) (2 min recovery)
	3 X 20 m sprints (100%) (1 min recovery)
	1 x 200 m (100%) (2 min recovery)
	1 x 400 m (100%)
Warm-down (for all sessions)	Easy jogging (800 m)
	Stretching

4.4.4 Weight training program for power/strength athletes:

Performed 3 times per week on alternate days to running program, alternate between workout 1 and workout 2.

5

Body Part	Exercise	WORKOUT 1 Sets (x reps)	WORKOUT 1 Resistance	WORKOUT 2 Sets (x reps)	WORKOUT 2 Resistance
Warm up	5 min slow jog				
	Stretching				
Upper body	Bench press	3 (to failure)	90% 1 RM	3 x 20 (or failure)	35% 1 RM (fast)
	Chin ups	3 (to failure)	90% 1 RM (weight around waist)	3 (to failure)	Body weight
	Parallel	3 (to failure)	90% 1 RM (weight around	3 x 20 (or	35% 1 RM

	dips		waist)	failure)	(fast)
	Biceps curls	3 (to failure)	90% 1 RM	3 x 20 (or failure)	35% 1 RM (fast)
Abdominals	Sit ups	3 x 12	Incline required to cause failure at 12 repetitions in final set	3 x 20 (or failure)	No incline, fast.
	Bent knee raises	3 x 20 (fast)	Weight of own legs	3 x 20 (fast)	Weight of own legs
	Twisting sit ups	3 x 10 (each side)	Incline required to cause failure at 5 repetitions in final set	3 x 20 (or failure)	No incline, fast.
Lower Body	Leg press	3 (to failure)	90& 1 RM	3 x 20 (or failure)	35% 1 RM (fast)
	Knee extension	3 (to failure)	90% 1 RM	3 x 20 (or failure)	35% 1 RM (fast)
	Leg curls	3 (to failure)	90% 1 RM	3 x 20 (or failure)	35% 1 RM (fast)
	Calf raises	3 (to failure)	90% 1 RM	3 x 20 (or failure)	35% 1 RM (fast)
Warm-down	5 min slow jog				
	Stretching				

5. Supplement Preparation

The bovine colostrum used as the supplement in the present study was prepared according to the patented processes as outlined in Australian Patents 644468, 668033 and New Zealand Patents 239466, 260568 the contents of which are incorporated herein by reference.

The colostrum from up to the first six milkings following calving

was collected.

The colostrum was warmed to 55°C and skimmed in a standard dairy separator to reduce fat.

The skimmed colostrum was then pasteurised at 63°C for 30 min (standard temperature x time combination meeting Australian export requirements and Food and Drug Authority standard pasteurising conditions) and/or centrifuged at 12, 000 g in a Bactofuge to reduce bioburden.

The pasteurised colostrum was then ultrafiltered to reduce water, lactose and electrolyte levels in order to concentrate the protein content.

The concentrate was then spray dried in an aseptic, pharmaceutical model 2 stage spray drier with a filtered air supply to produce colostrum powder (powder production accords with the Code of Good Manufacturing Practice for Therapeutic Goods in Australia).

The supplements were mixed with skimmed milk/water and taken orally.

6. Feeding Protocol

Subjects consumed two doses of supplement per day with their morning (20 gms) and evening (40 gms) meals. Each dose was added to 85 mls of warm water and mixed thoroughly.

7. Statistical Analysis of Data

7.1 Sample size

A total of 40 subjects, 20 EA and 20 PSA were organised into experimental group (10) and a placebo group (10).

8. Data Analysis

Differences in primary and secondary study parameters were compared between groups using two-way analysis of variance with repeated measures and students *t* -tests.

Regression analyses was performed where appropriate to examine relationships between variables.

8.1 Primary and Secondary Study Parameters

The primary parameters used throughout this study were exercise

performance, fatigue, plasma IGF-I and body composition.

The secondary parameter was a measurement of the creatine kinase levels.

RESULTS

1. ENDURANCE ATHLETES

1.1 Subjects

Of the 20 subjects who commenced in the study 14 completed all of the requirements. Of these, 8 were on the colostrum supplement and 6 were on the placebo. Table 1 below indicates the reasons for the exclusion/withdrawal of the 6 subjects who did not complete the study:

Table 1. - Reasons for exclusion/withdrawal of subjects who did not complete all of the requirements of the study

Colostrum Group	Placebo Group
Relationship breakdown during study (n=1)	Vomited on drinking the supplement (n=1)
Flu/viral illness (n=1)	Work commitments and non-compliance with alcohol exclusion criteria (n=1)
	Viral illness (n=2)

Two subjects data (1 Colostrum, 1 Placebo) were included in the analysis on an intention to treat basis. The data for these subjects have been included only where a statistically significant difference was found between the two groups using the data of those subjects who completed all aspects of the study since both of these subjects fell ill during the study and the effect of the illness on their performances is unclear.

1.2 General Anthropometric Characteristics

Some general anthropometric and characteristics of the subjects from the first testing trial are given in Table 2 below:

Table 2. Subject general anthropometric characteristics at Trial 1

Characteristic	Colostrum Group (n=8)	Placebo group (n=6)	Statistical significance
Age (yrs)	26.48 ± 1.52	24.71 ± 2.03	NS, P=0.50
Mass (kg)	77.17 ± 2.91	73.86 ± 3.12	NS, P=0.45
Height (cm)	180.96 ± 1.39	175.47 ± 1.88	Significant, P=0.04

As can be seen from the data in Table 2, the athletes in the colostrum group were slightly taller than the athletes in the placebo group, but were no different in terms of age or body mass.

1.3 Blood Pressure

There was no difference in either systolic (Colostrum 128.13 ± 3.44 mmHg; Placebo 126.83 ± 5.86 mmHg; P=0.85) or diastolic (Colostrum 76.88 ± 2.92 mmHg; Placebo 78.17 ± 4.83 mmHg; P=0.82) blood pressures between the two groups at Trial 1. Systolic blood pressure did not change in either group during the study, but diastolic blood pressure decreased in both groups, reaching 70.00 ± 2.25 mmHg and 70.17 ± 3.19 mmHg in the colostrum and placebo groups respectively by the end of the study, with these values not being statistically different (P=0.97).

1.4 Thigh and Calf Girths

Thigh and calf girths are summarised in Tables 3 and 4 below. There were no differences in thigh or calf girths between the two groups (P>0.05) at any time during the study, and neither changed in either group during the study (P>0.05).

Table 3. Thigh girths

	Trial 1	Trial 2	Trial 3
Colostrum Group			
Left thigh girth (cm)	51.55 ± 1.33	51.40 ± 1.30	52.00 ± 1.19
Right thigh girth (cm)	52.19 ± 1.36	52.03 ± 1.44	52.29 ± 1.29
Placebo Group			
Left thigh girth (cm)	52.15 ± 1.01	51.88 ± 1.13	51.83 ± 1.34
Right thigh girth (cm)	51.77 ± 0.74	51.80 ± 0.83	51.92 ± 1.00

Table 4. Calf girths

	Trial 1	Trial 2	Trial 3
Colostrum Group			
Left calf girth (cm)	36.84 ± 0.75	36.83 ± 0.89	37.19 ± 0.78
Right calf girth (cm)	37.24 ± 0.83	37.60 ± 0.97	37.60 ± 0.85
Placebo Group			
Left calf girth (cm)	37.17 ± 1.09	37.13 ± 1.15	37.45 ± 1.18
Right calf girth (cm)	37.38 ± 1.10	36.97 ± 1.23	37.60 ± 1.21

1.5 Body Composition

1.5.1 Percentage Body Fat (%BF)

There was no difference in %BF between the two groups at Trial 1 (Colostrum 16.69 ± 1.62 %, Placebo 14.67± 1.54 %; P=0.36). During the study %BF decreased in both groups (P=0.02), but by the same amount (P=0.72) such that there was no difference between the values reached in either group by the end of the study (Colostrum 15.34 ± 1.49 %; Placebo 13.15 ± 1.33 %; P=0.30). The change in %BF for each group is shown in Figure 1.

1.5.2 Fat Mass (FM)

Since there was no difference in body mass or %BF between the two groups at Trial 1, there was also no difference in FM (Colostrum 13.18 ± 1.56 kg, Placebo 10.94 ± 1.55 kg; P=0.33) and, just as %BF decreased by the same amount in both groups, FM also decreased (P=0.04) by the same amount in both groups (P=0.68) (see Figure 2).

1.5.3 Fat-Free Mass (FFM)

There was no difference in FFM between the two groups at trail 1 (Colostrum 63.98 ± 1.80 kg, Placebo 62.92 ± 2.30 kg; P=0.72). FFM increased significantly in both groups during the study (P=0.02), but by the same amount in both groups (P=0.23), reaching 64.76 ± 1.84 kg and 63.22 ± 2.50 kg in the colostrum and placebo groups respectively by the end of the study. The changes in FFM are shown in Figure 3.

1.5.4 Treadmill Running Tests

Table 5 shows the treadmill running performance characteristics of the subjects at Trial 1.

Table 5. Running performance characteristics at Trial 1

	Colostrum Group	Placebo Group	Statistical significance
Maximal oxygen uptake ($ml \cdot kg^{-1} \cdot min^{-1}$)	51.87 ± 2.22	55.06 ± 3.04	P=0.42
Maximum heart rate (bpm)	196.4 ± 3.4	192.8 ± 4.0	P=0.52
Oxygen uptake at lactate threshold ($ml \cdot kg^{-1} \cdot min^{-1}$)	37.47 ± 1.87	42.90 ± 1.87	P=0.06 (t-test) P=0.03 (ANOVA)
Distance covered during first run (m)	4083.33 ± 502.72	4555.56 ± 776.88	P=0.62
Work done during first run (kJ)	122.23 ± 32.99	146.92 ± 47.23	P=0.68
Distance covered during second run (m)	3458.33 ± 535.45	4027.78 + 781.04	P=0.56
Work done during second run (kJ)	90.55 ± 32.10	117.48 + 41.88	P=0.62
Distance covered during second run as % of first run	83.13 ± 3.09	86.32 ± 3.82	P=0.53
Work done during second run as % of first run	67.53 ± 5.52	73.52 ± 7.30	P=0.53
Combined distance covered in both runs (m)	7541.67 ± 1033.42	8583.33 ± 1554.27	P=0.59
Combined work done during both runs (kJ)	212.78 ± 64.89	264.40 ± 88.92	P=0.65

As can be seen from Table 5, there was no difference in maximal oxygen uptake between the two groups at Trial 1. Maximal oxygen uptake did not change significantly in either group during the 8 week study period (P=0.22).

There was no difference in maximum heart rate between the two groups at Trial 1. Maximum heart rate decreased in both groups during the study (P=0.003) but to the same extent in both groups (P=0.23), reaching 191.8 ± 2.9 bpm in the colostrum group and 189.83 ± 3.0 bpm in the placebo group by the end of the 8 weeks.

Whether or not there was a difference in oxygen uptake at the lactate threshold between the two groups depends on the statistic that is used. Analysis of the values at the start of the study using an unpaired t-test shows no difference in oxygen uptake at the lactate threshold between the two groups (P=0.06). However, this statistic seems unconvincing when one considers that the result is bordering on statistical significance and analysis of the oxygen uptake at the lactate threshold using a two-way ANOVA (repeated measures) over all 3 trials showed a statistically significant difference between the two groups (P=0.03) with no significant change during the 8 week study period (P=0.95) (see Figure 4). The difference in statistical outcomes, depending on the test used, is a result of the relatively low number of athletes who completed the study.

There was no difference in the distance covered during the first treadmill run between the two groups at Trial 1 and, although the distance covered increased significantly in both groups during the 8 week study period (P<0.01), there was no difference in the extent of the increase between the two groups (P=0.43) such that the distance covered was the same in both groups by the end of the study (Colostrum 4885.42 ± 465.03 m, Placebo 5083.33 ± 654.75 m; P=0.70). However, although there was no statistically significant difference in the increase in distance covered during the study period there was a trend for the distance covered by the colostrum group to increase more, as can be seen in Figure 5.

Just as there was no difference in the distance covered in the first treadmill run between the two groups at Trial 1, there was also no difference in the work done during the first run between the two groups. The work done during the first run increased in both groups during the study (P<0.01), but by the same amount (P=0.21), such that there was no statistical difference between the two groups in terms of the improvement in work done during the 8 week study period (P=0.10), with the colostrum group doing 170.11 ± 35.38 kJ and the placebo group 174.34 ± 43.81 kJ of work during Trial 3. However, despite there being no statistical difference between the two groups, there was a trend for the increase in total work done to be greater in the colostrum group

(see Figure 6), such that, from Trial 1, there was an increase of 47.88 ± 9.09 kJ for the colostrum group and 27.42 ± 9.01 for the placebo group (see Figure 6).

There was no difference in the distance covered during the second treadmill run between the two groups at Trial 1. During the study period the distance covered during the second run increased significantly in both groups ($P<0.001$), but the extent of the increase was the same in both groups ($P=0.10$). When the data were normalised for the distance covered in Trial 1 it was found that the distance covered increased in both groups over the 8 week study period ($P=0.004$), but by significantly more in the colostrum group ($P=0.049$). When the data for the intention to treat subjects was included the significant increase in distance covered in both groups remained ($P<0.001$), and the extent of the increase was the same in both groups ($P=0.24$). However, when normalised for the distance covered in Trial 1, it was found that there was no longer a greater increase in the distance covered by the colostrum group ($P=0.17$) (see Figure 7).

There was no difference between the two groups in the amount of work done during the second run at Trial 1 (see Figure 8). During the study period the work done during the second run increased significantly in both groups ($P<0.001$), but the rate of increase was significantly greater in the colostrum group ($P=0.02$). When the data were normalised for the distance covered in Trial 1 the same relationship was found, work done increased significantly in both groups ($P=0.004$) with the colostrum group increasing their work output significantly more than the placebo group ($P=0.03$). When the data for the intention to treat subjects was included the work done still increased significantly in both groups ($P<0.001$), but the extent of the increase was not different ($P=0.09$), as was the case when the data were normalised for the work done during Trial 1 ($P=0.17$).

There was no difference between the two groups in terms of the distance covered in the second run as a percentage of the distance covered in the first run during Trial 1 (see Figure 9). There was a trend for the distance covered in the second run to increase as a percentage of the distance covered in the first run in both groups over the 8 week study period, but this was only a trend as it

did not reach statistical significance (P=0.07). When normalised for the values achieved in Trial 1 there was a trend for the colostrum group to increase more than the placebo group (P=0.10), but there was still no statistical difference between the two groups by the end of the study period (P=0.28, 2-tailed t-test).

There was no difference in the work done in the second run as a percentage of the work done in the first run between the two groups during Trial 1 (see Figure 10). There was a trend for the work done in the second run to increase as a percentage of the distance covered in the first run in both groups during the study period, but this did not reach statistical significance (P=0.07). When normalised for the work done in the first trial there was a further trend for the colostrum group to do more work in the second run as a percentage of the first run than the placebo group (P=0.09), but there was still no statistical difference between the two groups by the end of the study period (P=0.25, 2-tailed t-test).

There was no difference between the two groups in the total distance covered during both runs in Trial 1 (see Figure 11). The total distance covered in both runs increased significantly in both groups during the study period (P<0.001), but by the same amount in both groups (P=0.18) such that, despite there being a trend for a greater increase in the colostrum group, there was no statistical difference between the two groups by the end of the study period (P=0.15, 2-tail t-test).

There was no difference between the two groups in the total amount of work done during both runs at Trial 1 (see Figure 12). The total amount of work done during both runs increased in both groups during the study period (P<0.001), but the increase was more rapid in the colostrum group (P=0.04) such that the total amount of work done in both runs had increased significantly more in the colostrum group by the end of the study period (Colostrum group increased by 102.19 ± 15.10 kJ, Placebo group increased by 46.35 ± 16.46 kJ; P=0.03, 2-tailed t-test, Power = 0.62). When the data for the intention to treat subjects were added to the data the difference in the increase in total work done for both runs was still statistically significant, but less so than when the data for these subjects was not included (Colostrum group increased by 92.37

± 16.55 kJ, Placebo group increased by 44.52 ± 14.03 kJ; P=0.04, 2-tailed t-test, Power = 0.44).

There was no difference between the two groups in either the respiratory exchange ratios (RER; P=0.46) or blood lactate concentrations (P=0.79) during the first treadmill run at Trial 1. Neither the RER (Colostrum P=0.57; Placebo P=0.61) nor the blood lactate concentrations (Colostrum P=0.22; Placebo P=0.29) changed during the first treadmill run in either group by the end of the study.

There was no difference between the two groups in either the respiratory exchange ratios (RER; P=0..86) or blood lactate concentrations (P=0.58) during the second treadmill run at Trial 1. Neither the RER (Colostrum P=0.44; Placebo P=0.22) nor the blood lactate concentrations (Colostrum P=0.28; Placebo P=0.32) changed during the second treadmill run in either group by the end of the study.

1.6 Biochemistry

1.6.1 Plasma IGF-I

There was no difference in plasma IGF-I concentrations between the two groups at Trial 1 (Colostrum 198.50 ± 8.84 mg/ml, Placebo 219.33 ± 18.87 ng/ml; P= 0.35) and plasma IGF-I concentrations did not change significantly during the 8 week study period in either group (P>0.05) (see Figure 13).

1.6.2. Serum Creatine Kinase (CK)

There was no difference in pre-exercise serum CK concentrations between the two groups at Trial 1 (Colostrum 150.87 ± 19.89 U/L, Placebo 197.87 ± 53.04 U/L; P=0.44) and these values did not change significantly in either group during the study period (see Figure 14).

During Trial 1 the two treadmill runs resulted in increased serum CK concentrations in both groups, with CK levels increasing by 59.75 ± 15.15 U/L in the colostrum group and 40.67 ± 4.58 U/L in the placebo group. Normalising the increases in serum CK for the amount of work done during the running tests showed that the increase in CK per unit work done was not statistically different between the two groups at Trial 1 (Colostrum 0.46 ± 0.22 U/L/kJ, Placebo 0.29 ± 0.07 U/L/kJ; P=0.49). The increase in serum CK per unit work done did not

change significantly in either group during the study (P=0.35), but there was a trend indicating that the increase was less in the colostrum group (see Figure 14).

1.6.3 Intestinal permeability

There was no difference in intestinal permeability as measured by the lactulose:rhamnose (Colostrum 0.07 ± 0.02, Placebo 0.11 ± 0.03; P=0.23) or the lactulose:mannitol (Colostrum 0.02 ± 0.00, Placebo 0.06 ± 0.02; P=0.48) ratios in the urine between the two groups at Trial 1. Neither the lactulose:rhamnose ratio (P=0.95) nor the lactulose:mannitol ratio (P=0.52) changed during the study period (see Figure 15 and 16).

1.6.4 Dietary Food Intake

There was no difference in mean daily energy intake per kg body mass between the two groups during the first 4 weeks of the study (Colostrum 127.38 ± 3.45 kJ/kg, Placebo 135.41 ± 6.58 kJ/kg; P=0.31) and this level of energy intake did not change during the remainder of the study in either group (P=0.79).

There were no differences in carbohydrate, protein or fat intakes between the two groups during the study (P>0.05). During the first 4 weeks of the study the colostrum group had carbohydrate, protein and fat intakes which constituted 44.54 ± 1.54 %, 29.63 ± 0.59 % and 25.82 ± 1.58 % of their diets respectively, and these values did not change during the remainder of the study (P>0.05). During the first 4 weeks of the study the placebo group had carbohydrate, protein and fat intakes which constituted 44.80 ± 3.16 %, 29.39 ± 1.08 % and 25.81 ± 2.76 % of their diets respectively, and these values did not change during the remainder of the study (P>0.05).

DISCUSSION

This study examines the effect of oral bovine colostrum supplementation on endurance exercise performance. The principal finding of the present study was that in athletes undertaking an endurance training program oral supplementation with bovine colostrum resulted in a significantly greater increase in endurance capacity than was achieved using an oral protein

supplement. Apart from the supplementation, this effect was not due to differences in dietary intake between the two groups because the dietary intakes were the same.

Throughout the period of the study there was a trend for the athletes taking the colostrum supplements to increase the distance covered during the first of the two treadmill runs at each trial, but this trend did not reach statistical significance. However, the athletes taking the colostrum supplement did demonstrate significantly greater increases in the distance covered and the amount of work done during the second treadmill runs at each trial. As a result of the greater increase in the work done during the second treadmill runs at each trial there was also a significantly greater increase in the total work done during both runs at each trial in the colostrum group.

The finding of no significant difference in performance between the two groups during the first treadmill run at each trial (although there was a trend suggesting that performances were improved) but a significantly greater improvement in the colostrum group during the second run suggests that although there may be some performance enhancing effect of colostrum supplementation, there is apparently a greater effect in terms of improving recovery from previous exercise. The mechanism for this enhanced recovery is not immediately apparent from the data collected in the present study since there were no differences in blood lactate or RER responses during the second treadmill runs between the two groups at any of the trials. There was however, a trend for the CK values to be less elevated at the end of each trial in the colostrum group (see Figure 14) and it is possible that a reduced level of muscle damage caused in the first treadmill run could have assisted the subjects on the colostrum supplement in sustaining performing better in the second treadmill run. However, it cannot be ruled out that some other parameter which was not measured could have led to the greater improvement in these subjects.

Unlike in the power athletes, bovine colostrum supplementation did not appear to enhance any of the positive effects on body composition which occurred during training. However, just as was the case in the power athletes

there was no change in plasma IGF-I concentrations in response to taking bovine colostrum supplements, despite the fact that it has been shown that orally administered ^{125}I-IGF is transported into the circulation in calves (1). As was suggested in the report discussing the effect of oral bovine colostrum in power athletes, the lack of an increase in plasma IGF-I could be interpreted as indicating that it is not this hormone which is responsible for the improvements in exercise performance.

In summary, this study provides evidence that oral supplementation with bovine colostrum can enhance increases in endurance capacity beyond those which will ordinarily be achieved through training alone.

2. POWER ATHLETES

2.1 Subjects

Of the 20 subjects who commenced in the study 12 completed all of the requirements. Of these, 7 were on the colostrum supplement and 5 were on the placebo. Table 6 below indicates the reasons for the exclusion/withdrawal of the 8 subjects who did not complete the study:

Table 6. - Reasons for exclusion/withdrawal of subjects who did not complete all of the requirements of the study

Colostrum Group	Placebo Group
Non-compliance with training/family death (n=1)	Torn hamstring (n=2)
Leg injury (shin splints) (n=1)	Non-compliance with training and supplement use (n=1)
Vomited on drinking the supplement (n=1)	Groin injury (n=1)
	Viral illness (n=1)

Two subjects data (1 Colostrum, 1 Placebo) were included in the analysis on an intention to treat basis. The data for these subjects have been included only where a statistically significant difference was found between the

two groups using the data of those subjects who completed all aspects of the study since both of these subjects were injured during the study and the effect of the injuries on their performances is unclear.

2.2 General Anthropometric Characteristics

Some general anthropometric and characteristics of the subjects from the first testing trial are given in Table 7 below:

Table 7. General anthropometric characteristics at Trial 1

Characteristic	Colostrum Group (n=7)	Placebo group (n=5)	Statistical significance
Age (yrs)	22.92 ± 1.62	23.35 ± 1.93	NS; P=0.87
Mass (kg)	71.25 ± 3.28	81.67 ± 4.45	NS; P=0.10
Height (cm)	176.37 ± 3.25	178.97 ± 3.69	NS; P=0.61

2.3 Blood Pressure

There was no difference in either systolic (Colostrum 131.43 ± 2.52 mmHg; Placebo 126.40 ± 4.79 mmHg; P=0.39) or diastolic (Colostrum 76.14 ± 3.43 mmHg; Placebo 77.20 ± 4.88 mmHg; P=0.86) blood pressures between the two groups at Trial 1 and neither pressure changed significantly in either of the two groups during the study (P>0.05).

2.4 Thigh and Calf Girths

Thigh and calf girths are summarised in Tables 8 and 9 below. There was no difference in thigh girths between the two groups at any time during the study (P>0.05) and thigh girths did not change in either group during the study (P>0.05). Similarly, there was no difference in calf girths between the two groups (P>0.05), but calf girths increased in both groups during the study (P=0.04). However, the increase was the same in both groups (P>0.05).

Table 8. Thigh girths

	Trial 1	Trial 2	Trial 3
Colostrum Group			
Left thigh girth (cm)	51.81 ± 1.80	51.93 ± 1.68	52.77 ± 1.72
Right thigh girth (cm)	51.44 ± 1.33	52.21 ± 1.60	52.64 ± 1.66
Placebo Group			
Left thigh girth (cm)	55.56 ± 1.83	56.26 ± 1.50	56.50 ± 1.32
Right thigh girth (cm)	56.08 ± 1.64	55.80 ± 1.21	56.2 ± 1.28

Table 9. Calf girths

	Trial 1	Trial 2	Trial 3
Colostrum Group			
Left calf girth (cm)	35.83 ± 0.94	36.10 ± 0.86	36.44 ± 0.98
Right calf girth (cm)	36.11 ± 0.87	36.39 ± 0.77	36.69 ± 0.82
Placebo Group			
Left calf girth (cm)	37.96 ± 1.07	38.26 ± 0.90	38.26 ± 0.94
Right calf girth (cm)	37.80 ± 1.25	37.94 ± 1.04	37.86 ± 1.14

2.5 Body Composition

2.5.1 Percentage body fat (%BF)

There was no difference in %BF between the two groups at Trial 1 (Colostrum 11.21 ± 2.52 %, Placebo 14.44 ± 2.57 %; P=0.39). During the study %BF decreased in both groups (P=0.04), but by the same amount (P=0.26) such that there was no difference between the values reached in either group by the end of the study (Colostrum 9.73 ± 2.10 %; Placebo 13.98 ± 2.06 %; P=0.18). However, despite there being no statistical difference in the decrease in %BF between the two groups there was a trend for a greater reduction in the colostrum group as can be seen in Figure 17.

2.5.2 Fat Mass (FM)

Given that there were no differences in body mass or %BF between the two groups at Trial 1, there was also no difference in FM (Colostrum 8.14 ± 1.92 kg, Placebo 11.75 ± 2.21 kg; P=0.25). FM did not change in either group (P=0.08) but, as can be seen from Figure 18 there was a trend for a decrease in both groups, with the decrease being greater in the colostrum group.

2.5.3 Fat-Free Mass (FFM)

There was no difference in FFM between the two groups at Trial 1 (Colostrum 63.11 ± 3.09 kg, Placebo 69.92 ± 4.56 kg; P=0.26). FFM increased significantly during the study (P=0.001), but by the same amount in both groups (P=0.25). By the end of the 8 week study period FFM had increased to 64.91 ± 3.20 kg in the colostrum group and 70.80 ± 4.55 kg in the placebo group. Despite there being no statistical difference in the increase in FFM between the two groups, there was a trend for the increase to be greater in the colostrum group (see Figure 19).

2.6 Exercise Test Battery Performance Measures

2.6.1 20 m Sprint Times

The best 20 m sprint times achieved during the first and second attempts at each trial were not different in either of the two groups (P>0.05). Sprint times decreased significantly in the placebo group during the study period (P=0.01), but did not change in the colostrum group (P=0.18). Inclusion of the data for the intention to treat subjects strengthened this relationship with the reduction in sprint times for the placebo group being more statistically significant (P=0.004) whilst there was still no change in sprint times in the colostrum group

(P=0.38).

Table 10. Colostrum group best 20 m sprint times from first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (sec)	3.08 ± 0.05	3.15 ± 0.04	3.13 ± 0.05
Second attempts (sec)	3.12 ± 0.05	3.16 ± 0.04	3.11 ± 0.04

Table 11. Placebo group best 20 m sprint times from first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (sec)	3.24 ± 0.08	3.23 ± 0.08	3.17 ± 0.08
Second attempts (sec)	3.26 ± 0.08	3.26 ± 0.09	3.21 ± 0.08

When the best 20 m sprint times for each group of subjects during Trial 1 were analysed, whether achieved in the first or second attempts, there was no difference between the two groups (Colostrum 3.08 ± 0.05 sec, Placebo 3.23 ± 0.08 sec; P=0.16) and these values did not change significantly in either group during the study (P=0.18) (see Figure 20). However, despite a lack of statistical significance, there was a trend for the best 20 m sprint times to reduce in the placebo group and to increase in the colostrum group. Inclusion of the data for the intention to treat subjects did not change these relationships, 20m sprint times still did not change from the times achieved during Trial 1 in either group (P=0.18).

2.6.2 Alactic Anaerobic Power and Capacity

2.6.2.1 Alactic Power

The power outputs achieved during the first and second attempts at each trial were not different in either of the two groups (P=0.114). Power

outputs increased significantly in the colostrum group during the study period ($P<0.001$), but did not change in the placebo group ($P=0.41$). These relationships remained consistent when the data for the intention to treat subjects were included, with the power outputs still increasing significantly in the colostrum group ($P<0.001$), but not in the placebo group ($P=0.24$).

Table 12. Colostrum group alactic anaerobic power outputs during first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (W/kg)	17.58 ± 0.97	18.37 ± 0.81	19.07 ± 0.60
Second attempts (W/kg)	17.82 ± 0.98	18.29 ± 0.49	19.44 ± 0.77

Table 13. Placebo group alactic anaerobic power outputs during first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (W/kg)	16.23 ± 1.19	15.59 ± 0.93	16.24 ± 0.83
Second attempts (W/kg)	15.96 ± 1.15	16.51 ± 1.10	16.89 ± 1.20

When the highest alactic power outputs for each group of subjects during Trial 1 were analysed, whether the values were achieved in the first or second attempts, there was no difference between the two groups (Colostrum 18.21 ± 0.99 W/kg, Placebo 16.23 ± 1.19 W/kg; $P=0.23$) (see Figure 22). These power outputs increased in both groups during the study ($P=0.03$) reaching 19.64 ± 0.70 W/kg in the colostrum groups and 17.09 ± 1.19 W/kg in the placebo group, but there was no difference in the extent of the increase between the two groups ($P=0.70$) (see Figure 23). When the data for the intention to treat subjects was added to this analysis these relationships remained the same, there was still a significant increase in peak power outputs

in both groups (P=0.01), with no difference in the extent of the increase between the two (P=0.68).

2.6.2.2. Alactic Capacity

The alactic work outputs during the first and second attempts at each trial was not different in either of the two groups (P>0.05). The amount of work done during both attempts increased significantly in both groups during the study period (Colostrum P=0.001, Placebo P=0.003). These relationships remained consistent when the data for the intention to treat subjects was included, with alactic work outputs still increasing significantly in both groups (Colostrum P=0.001, Placebo P=0.001).

Table 14. Colostrum group alactic work outputs during first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (J/kg)	140.17 ± 6.41	146.78 ± 6.08	154.51 ± 5.11
Second attempts (J/kg)	140.62 ± 8.64	144.09 ± 4.22	152.24 ± 5.69

Table 15. Placebo group alactic work outputs during first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (J/kg)	130.23 ± 8.44	132.06 ± 8.54	141.24 ± 9.14
Second attempts (J/kg)	125.49 ± 7.32	131.96 ± 8.70	135.99 ± 8.03

When the peak alactic work outputs for each group of subjects during Trial 1 were analysed, whether achieved in the first or second attempts, there was no difference between the two groups (Colostrum 145.12 ± 7.23 J/kg, Placebo 130.23 ± 8.44 J/kg; P=0.21). The peak alactic work outputs increased in both groups during the study (P=0.001), but there was no difference in the

extent of the increase between the two (P=0.96). When the data for the intention to treat subjects was added to this analysis these relationships remained the same, there was still a significant increase in peak work outputs in both groups (P=0<0.001), with no difference in the extent of the increase between the two (P=0.83) (see Figures 24 and 25).

2.7. Vertical Jump

The vertical jump displacements achieved during the first and second attempts at each trial were not different in either of the two groups (P>0.05). Vertical jump displacement increased significantly in the colostrum group during the study period (P=0.03), but did not change in the placebo group (P=0.28). Inclusion of the data for the intention to treat subjects maintained this relationship, with the vertical jump displacement still increasing in the colostrum group (P=0.03), but not in the placebo group (P=0.37) (see Figure 26).

Table 16. Colostrum group vertical jump displacements during first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (J/kg)	42.76 ± 1.93	44.79 ± 2.10	47.33 ± 2.59
Second attempts (J/kg)	42.96 ± 2.04	44.66 ± 2.80	44.06 ± 2.35

Table 17. Placebo group vertical jump displacements during first and second attempts at each trial

	Trial 1	Trial 2	Trial 3
First attempts (J/kg)	41.16 ± 4.44	42.04 ± 4.93	42.52 ± 4.04
Second attempts (J/kg)	42.38 ± 4.23	40.24 ± 4.69	42.34 ± 3.86

When the greatest vertical jump displacements for each group of subjects during Trial 1 were analysed, whether achieved in the first or second

attempts, there was no difference between the two groups (Colostrum 43.43 ± 2.06 cm, Placebo 42.48 ± 4.20; P=0.85). The greatest vertical jump displacements increased in both groups during the study (P=0.05) reaching 47.36 ± 2.59 cm in the colostrum group 43.46 ± 3.99 cm in the placebo group by the end of the study, but there was no statistical difference in the extent of the increase between the two (P=0.25). Nevertheless, there was a definite trend for the colostrum group to increase their vertical jump displacement more than the placebo group (see Figure 27). When the data for the intention to treat subjects was included there was no longer a statistically significant increase in vertical jump displacement in either group (P=0.84).

2.8 Knee Extension and Flexion Peak Torques

The knee extension peak torques for both legs were added together to give the sum of knee extension peak torques for both legs. This same procedure was applied to the data for the knee flexion peak torques. There was no difference in the sum of either the knee extension or flexion peak torques between the two groups at any time during the study (P>0.05). The sum of knee extension torques did not change in either group during the study (P=0.17). Knee flexion torques on the other hand increased significantly in both groups (P=0.05), but there was no difference in the increase between the two (P=0.59).

Table 18. Knee extension sum of peak torques for both legs

	Trial 1	Trial 2	Trial 3
Colostrum group (N·m) (n=6)	441.92 ± 43.80	450.22 ± 39.21	449.92 ± 38.28
Placebo group (N·m) (n=5)	456.10 ± 37.98	491.58 ± 36.57	487.18 ± 41.40

Table 19. Knee flexion sum of peak torques for both legs

	Trial 1	Trial 2	Trial 3
Colostrum group (N·m) (n=6)	267.00 ± 23.52	294.74 ± 20.52	291.56 ± 23.48
Placebo group (N·m) (n=5)	294.20 ± 21.15	317.79 ± 29.03	302.04 ± 13.49

However, despite no statistical difference in the increase in knee extension peak torques between the two groups, as can be seen from Figure 28, there was a trend for the placebo group to increase their peak torques more than the colostrum group. No such trend was noted for knee flexion (see Figure 29).

2.9 Biochemistry

2.9.1 Plasma IGF-I

There was no difference in plasma IGF-I concentrations between the two groups at Trial 1 (Colostrum 179.71 ± 13.98 mg/ml, Placebo 200.80 ± 20.75 ng/ml; P= 0.43). Plasma IGF-I concentrations changed in both groups during the 8 week study period (P=0.05), initially decreasing slightly before exhibiting an increase, reaching 183.57 ± 14.18 ng/ml in the colostrum group and 220.20 ± 23.19 ng/ml in the placebo group by the end of the study. The changes in plasma IGF-I occurred in parallel in both groups (P=0.47) (see Figure 30).

2.9.2 Serum Creatine Kinase

There was no difference in pre-exercise serum CK concentrations between the two groups at Trial 1 (Colostrum 166.95 ± 38.41 U/L, Placebo 163.33 ± 30.89 U/L; P=0.94) and these values did not change significantly in either group during the study period (P=0.50). However, as can be seen from Figure 31, there was a trend for pre-exercise CK to increase in the placebo group, but not in the colostrum group.

Post-exercise serum CK concentrations were not significantly elevated from pre-exercise levels in either group by the performance of the exercise test batteries during the 3 trials (Colostrum P=0.39, Placebo P=0.63).

2.10 Dietary Food Intake

There was no difference in mean daily energy intake per kg body mass between the two groups during the study (P=0.65). During the first 4 weeks of the study the colostrum group had a mean daily energy intake of 135.17 ± 7.41 kJ/kg and the placebo group 147.06 ± 14.6 kJ/kg. These levels of energy intake did not change during the remainder of the study in either group (P=0.67).

There were no differences in carbohydrate, protein or fat intakes between the two groups during the study (P>0.05). During the first 4 weeks of the study the colostrum group had carbohydrate, protein and fat intakes which constituted 43.89 ± 2.00 %, 29.83 ± 1.23 % and 26.28 ± 1.73 % of their diets respectively, and these values did not change during the remainder of the study (P>0.05). During the first 4 weeks of the study the placebo group had carbohydrate, protein and fat intakes which constituted 45.93 ± 1.71 %, 27.83 ± 1.19 % and 26.23 ± 2.08 % of their diets respectively, and these values did not change during the remainder of the study (P>0.05).

3. DISCUSSION

The principal finding of the present study was that in athletes undertaking a power training program oral supplementation with bovine colostrum resulted in a significantly greater increase in vertical jumping performance than was achieved using an oral protein supplement. Taking oral supplements of bovine colostrum also resulted in a number of positive trends in terms of changes in body composition and protecting against exercise induced muscle damage. However, despite these positive effects, it was also found that whilst 20 m sprint times decreased in subjects taking the protein supplement (i.e. they ran faster), bovine colostrum supplementation prevented any such decrease, and there was also a trend for bovine colostrum supplementation to prevent increases in knee extension peak torques during contractions at 30°/sec. Apart from the supplementation, none of these effects were due to differences in dietary intake between the two groups.

The only other study which has investigated the effect of bovine

colostrum supplementation on the expression of muscle power [Mero, A. et al (1996)] found that colostrum supplementation resulted in a significant increase in serum IGF-I concentrations, but had no effect on muscle power, as measured using vertical jump displacement. The active component in bovine colostrum which is most likely to increase muscle power is IGF-I, since this hormone is known to have anabolic effects on skeletal muscle [Fryburg D.A. et al (1995); Tomas, F.M. et al (1991) (a) and Tomas, F.M. et al (1991)] However, despite reporting a significant increase in serum IGF-I concentrations, Mero et. al. found no improvement in vertical jumping performance. In the present study the reverse was true, no increase in plasma IGF-I concentrations were observed, but there was a significant improvement in vertical jumping performance, although the improvement in vertical jumping performances in the present study were more evident in terms of an increased consistency of performance for multiple jumps rather than an absolute increase in best vertical jumping performance at each trial (although there was a trend for the improvement in best jumping performance at each trial to also be higher in the colostrum group).

It was interesting to note that despite a much higher dose being administered for a much longer period of time in the present study Mero et al. found a significant increase in serum IGF-I concentrations whilst no effect on IGF-I concentrations in plasma was found in the present study.

In addition to the trend for a greater increase in FFM in the colostrum group there was also a trend for a greater decrease in %BF and FM in this group. However, there was a trend for %BF to decrease more in the colostrum group. Despite there being no statistical difference in these variables between the two groups the trends were all indicating positive changes and, given that it is known that IGF-I has an anabolic effect on skeletal muscle (6, 20, 21) and can increase fat metabolism [Tortora, G.J. et al (1996)] these trends can be adequately explained by the known actions of IGF-I.

During the study there was no significant increase in pre-exercise serum CK concentrations indicating that the training did not induce significant amounts of muscle damage in either group. However, despite the lack of statistical

significance there was a trend for serum CK values to increase in the placebo group, but not in the colostrum group

In summary, there are some encouraging trends in the data which suggest that oral supplementation can increase FFM and vertical jumping performance, and reduce %BF, FM and muscle damage during exercise. The improvement in vertical jumping performance is encouraging in terms of the ability to promote bovine colostrum as an ergogenic sports drink, but the effects on 20 m sprinting performance and knee extension peak torques are of some concern. Nonetheless, the trends for the positive effects on body composition are very exciting.

Finally, it is to be understood that various other modifications and/or alterations may be made without departing from the spirit of the present invention as outlined herein, and that these results will have application in patient groups outside athletes such as, but not restricted to, infant nutrition, catabolic states and fatigue.

DATED: 30 April, 1998

PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
NORTHFIELD LABORATORIES PTY LTD

David B Fitzpatrick

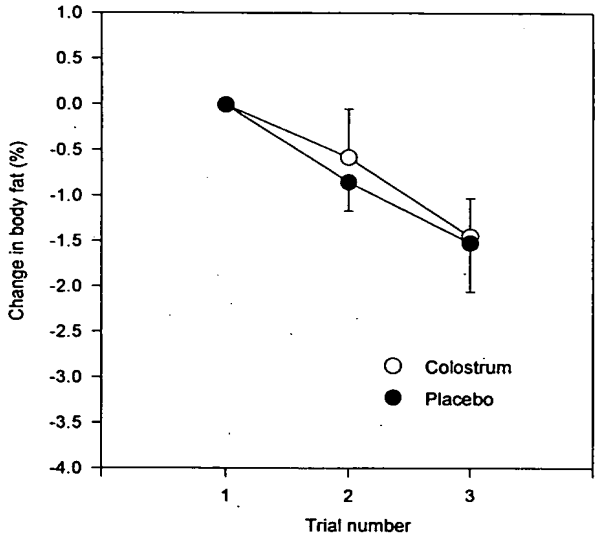

Figure 1. Change in percentage body fat

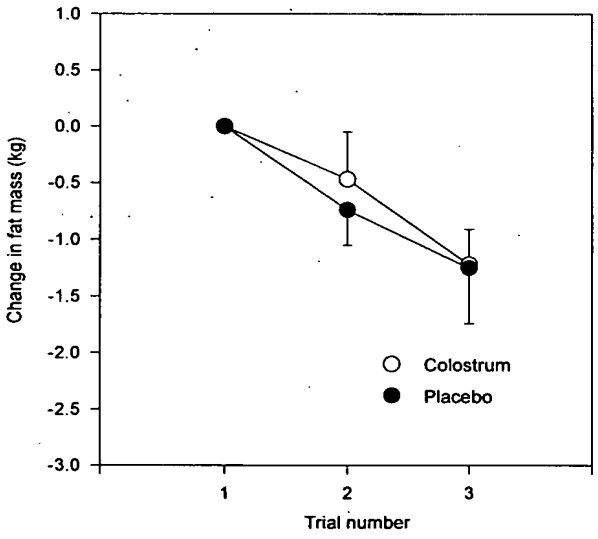

Figure 2. Change in fat mass.

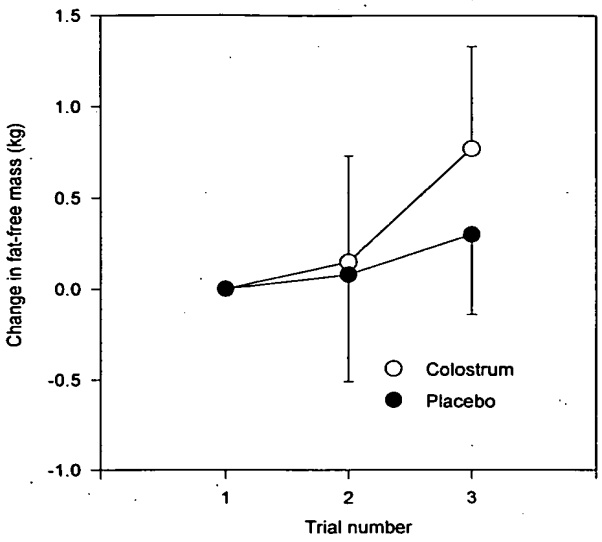

Figure 3. Change in fat-free mass.

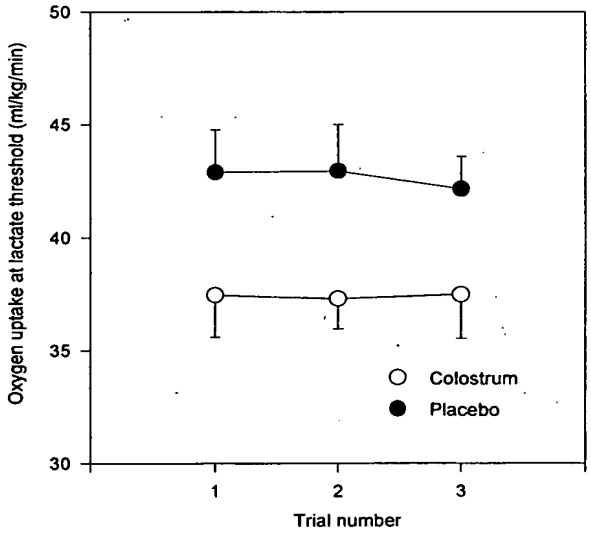

Figure 4. Oxygen uptake at the lactate threshold.

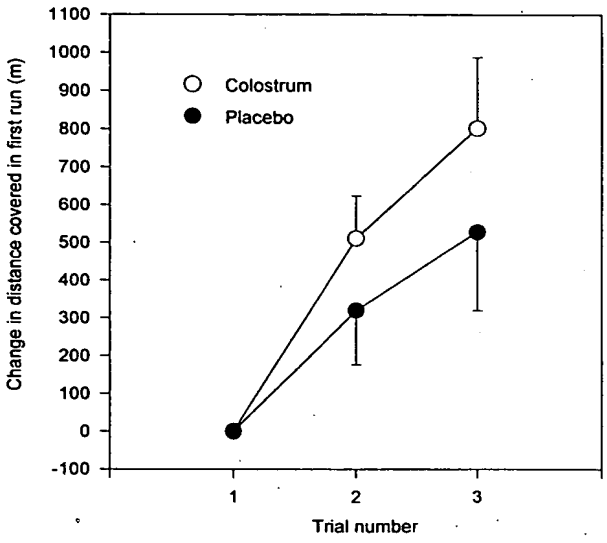

Figure 5. Change in distance covered in first treadmill run.

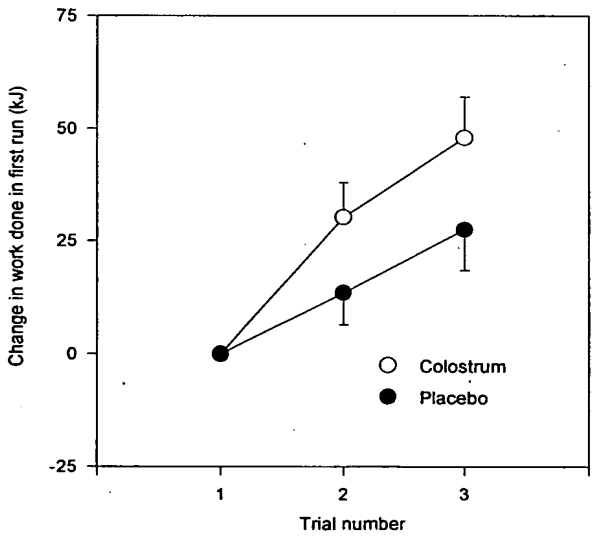

Figure 6. Change in work done during first treadmill run.

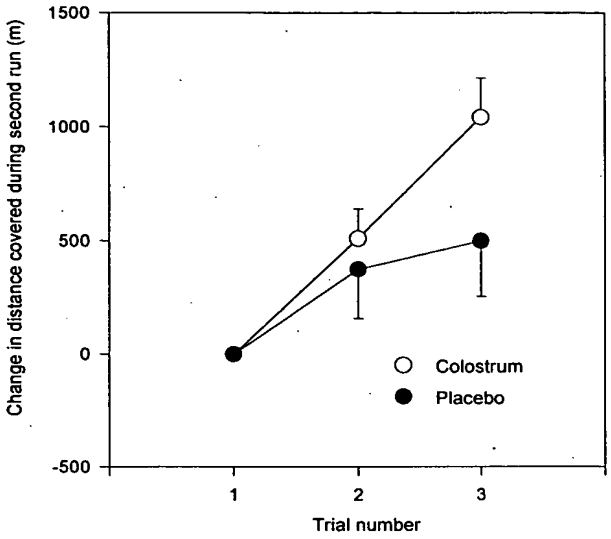

Figure 7. Change in the distance covered during the second treadmill run.

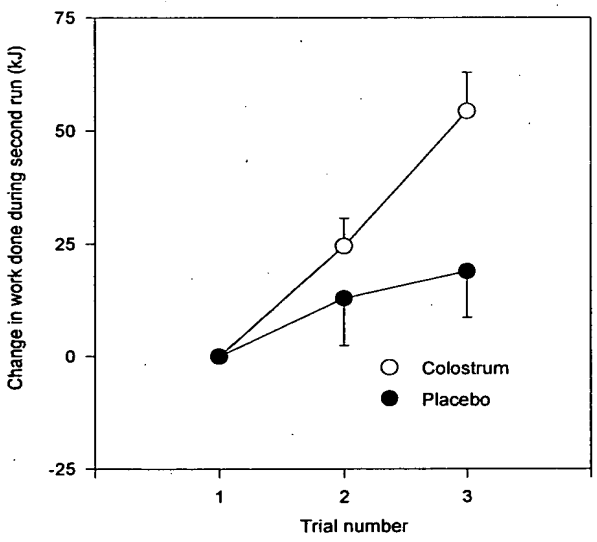

Figure 8. Change in the work done during the second treadmill run.

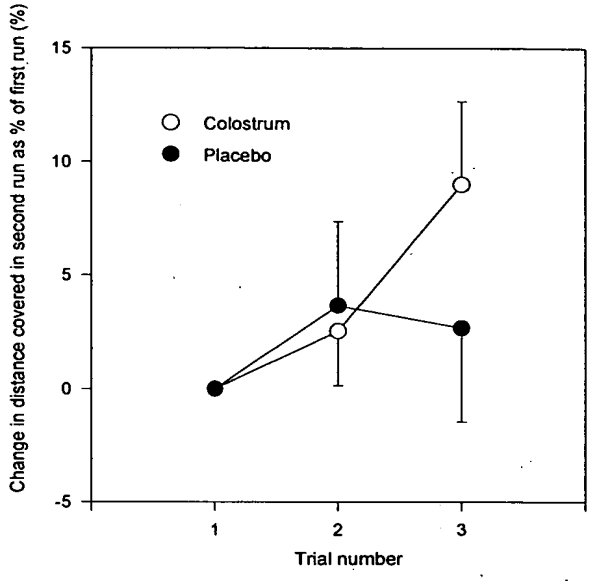

Figure 9. Change in the distance covered during the second treadmill run as a percentage of the distance covered during the first treadmill run.

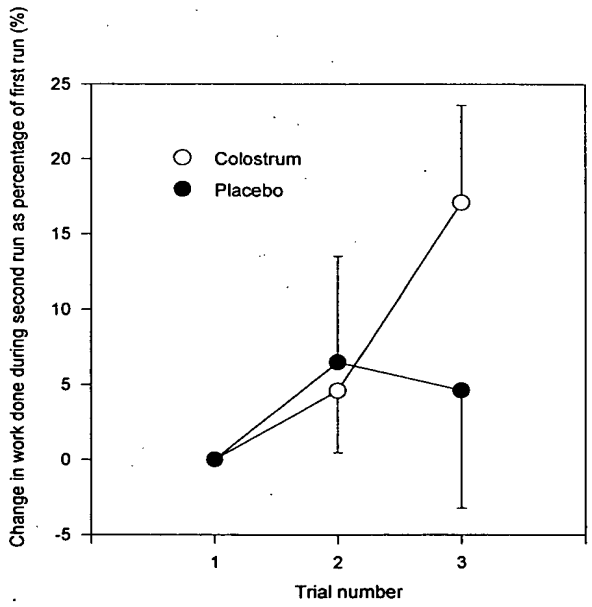

Figure 10. Change in the work done during the second treadmill run as a percentage of the work done during the first treadmill run.

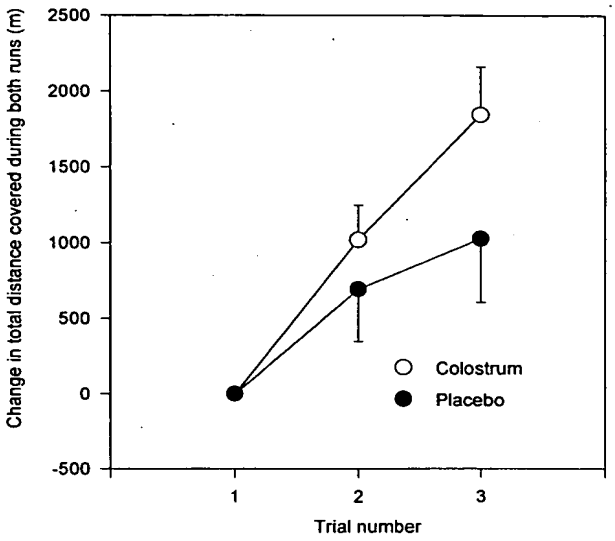

Figure 11. Change in the distance covered during both treadmill runs.

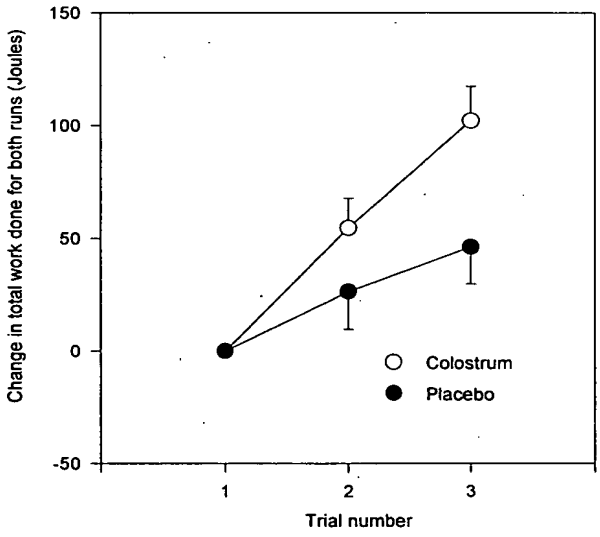

Figure 12. Change in the total work done during both treadmill runs.

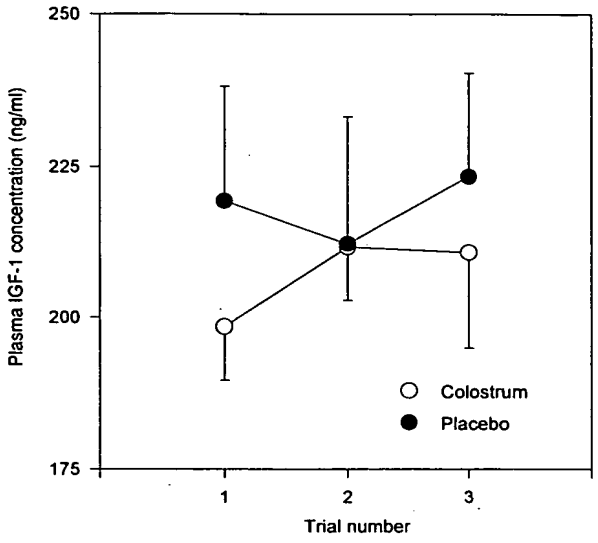

Figure 13. Plasma insulin-like growth factor 1 concentrations.

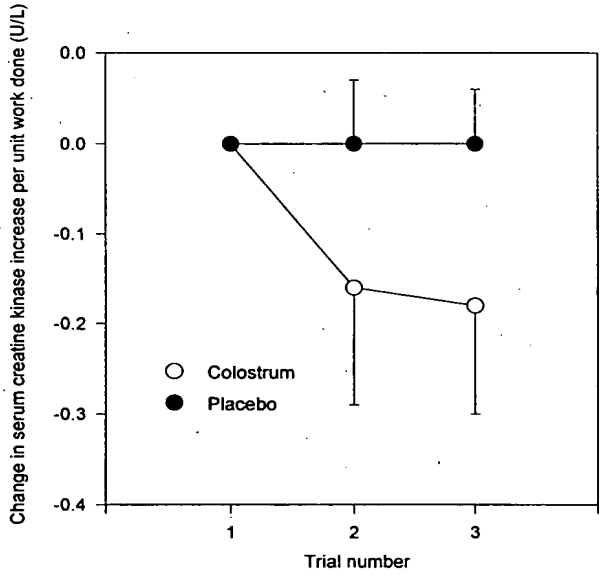

Figure 14. Change in the serum creatine kinase increase per unit work done in both runs.

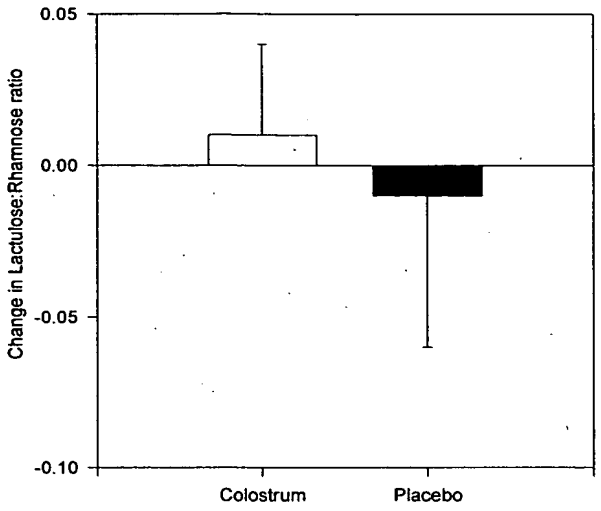

Figure 15. Change in the lactulose:rhamnose ratio during the 8 week study period.

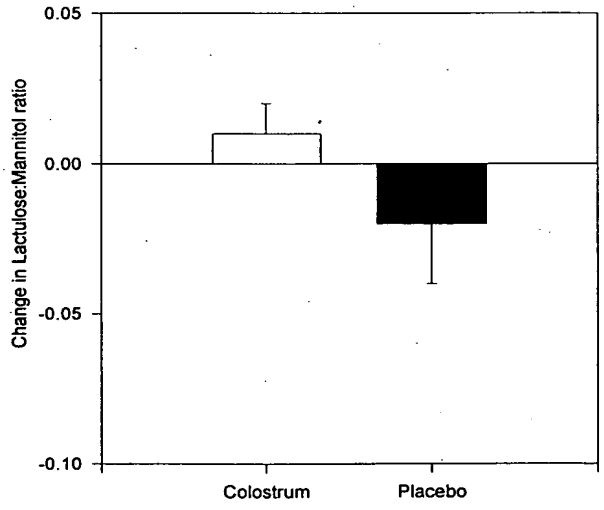

Figure 16. Change in the lactulose:mannitol ratio during the 8 week study period.

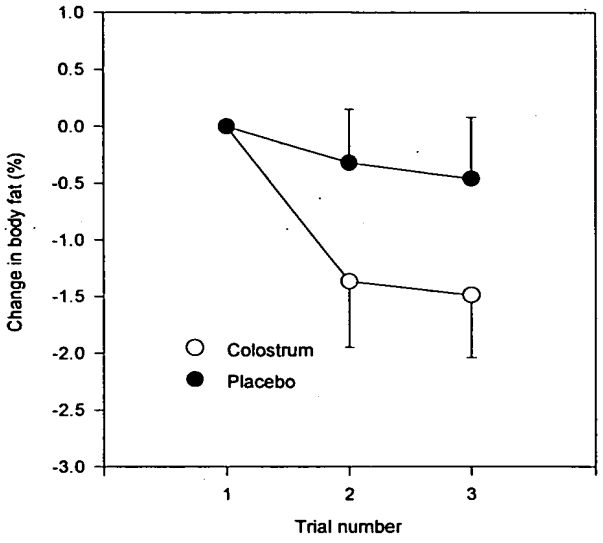

Figure 17. Change in percentage body fat

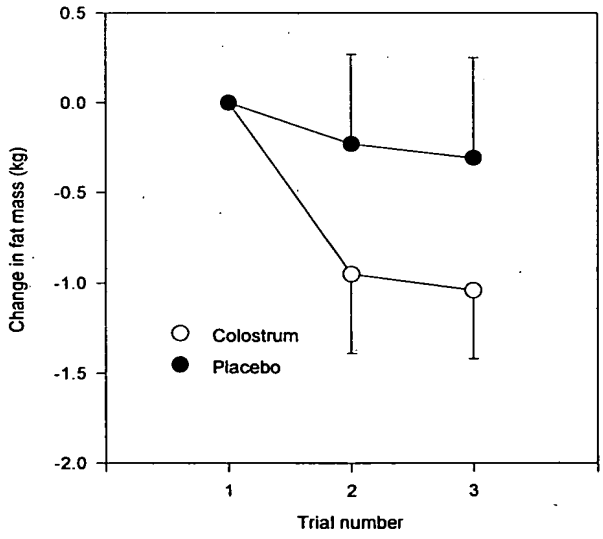

Figure 18. Change in fat mass

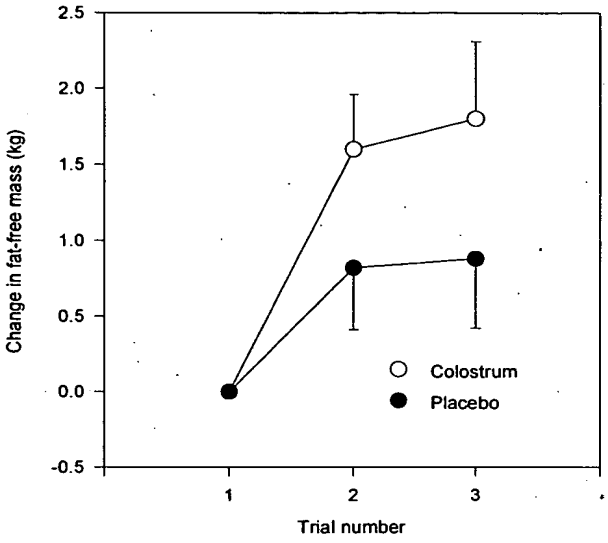

Figure 19. Change in fat-free mass

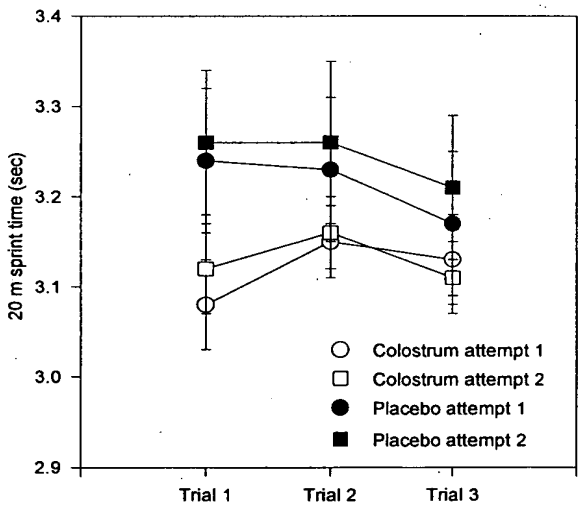

Figure 20. 20 m sprint times

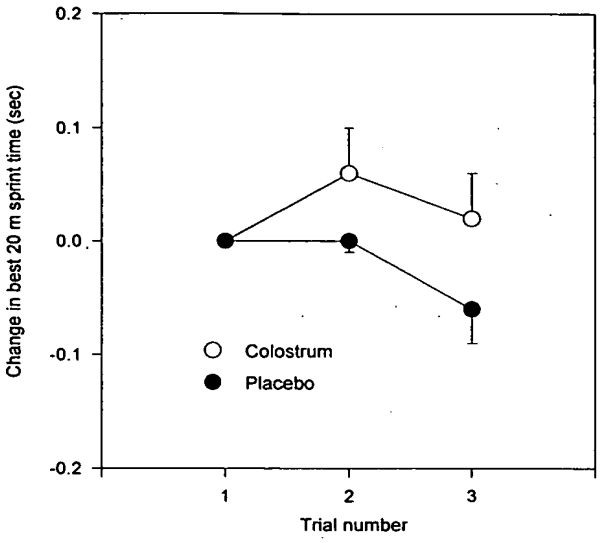

Figure 21. Change in best 20 m sprint times

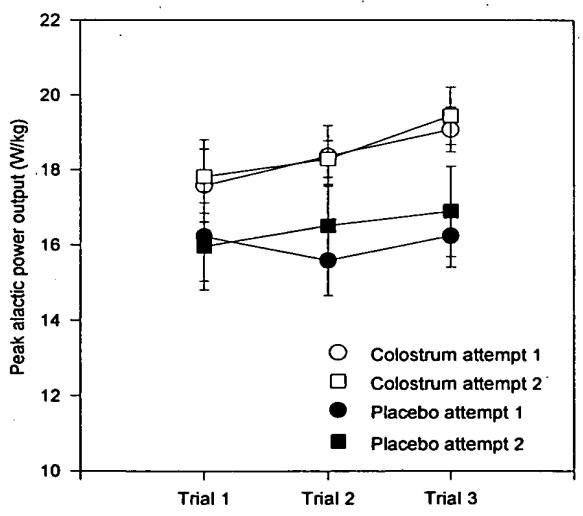

Figure 22. Alactic anaerobic power outputs (W/kg)

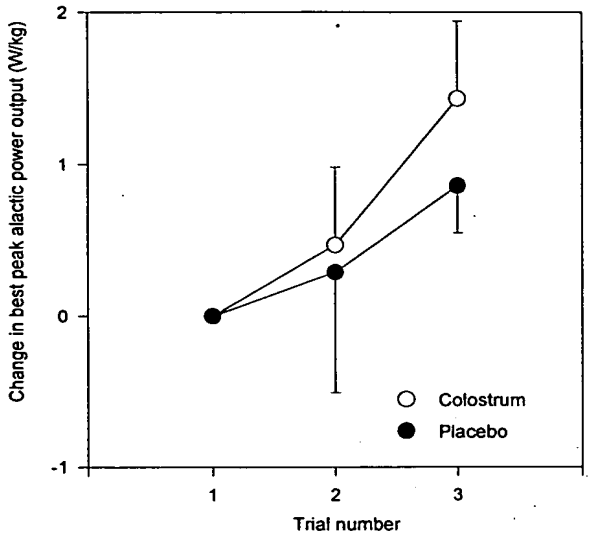

Figure 23. Change in highest alactic power outputs

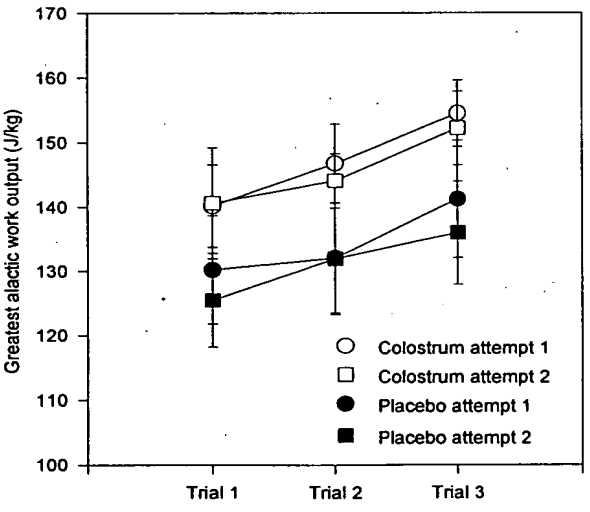

Figure 24. Alactic anaerobic work outputs (J/kg)

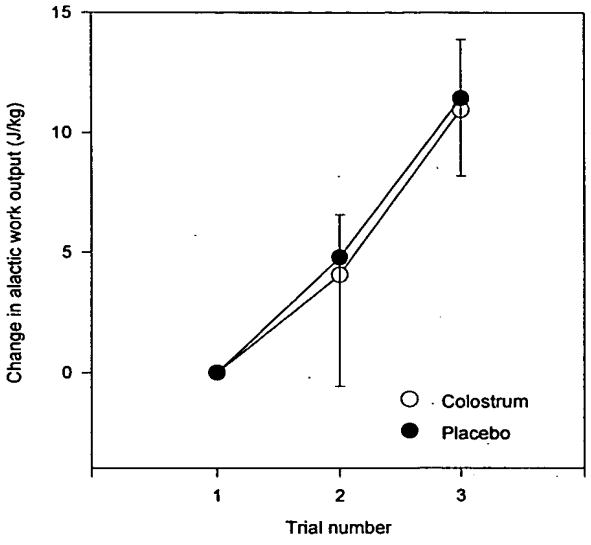

Figure 25. Change in best alactic work outputs

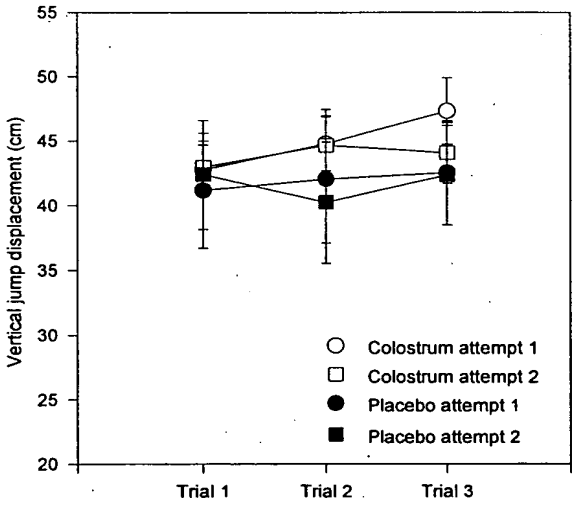

Figure 26. Vertical Jump displacement (cm)

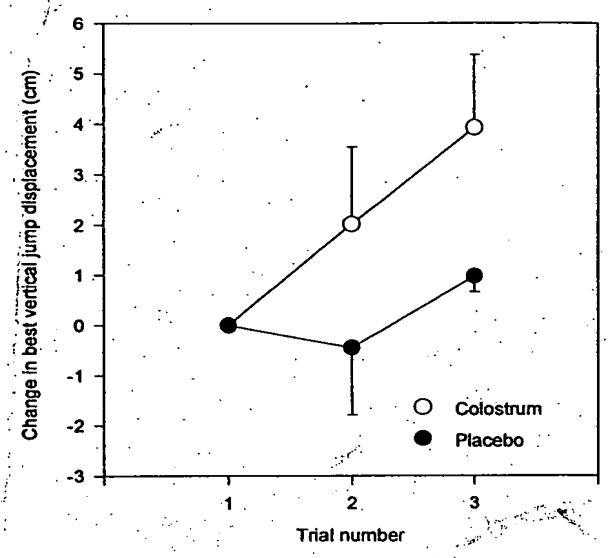

Figure 27. Change in best vertical jump displacement (cm)

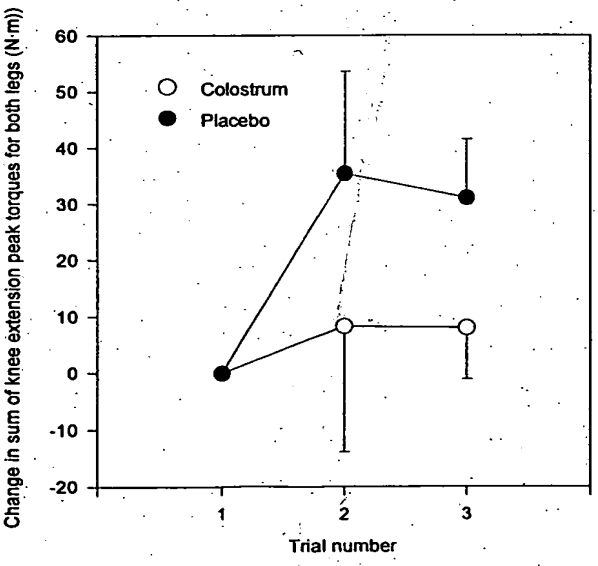

Figure 28. Change in sum of knee extension peak torques

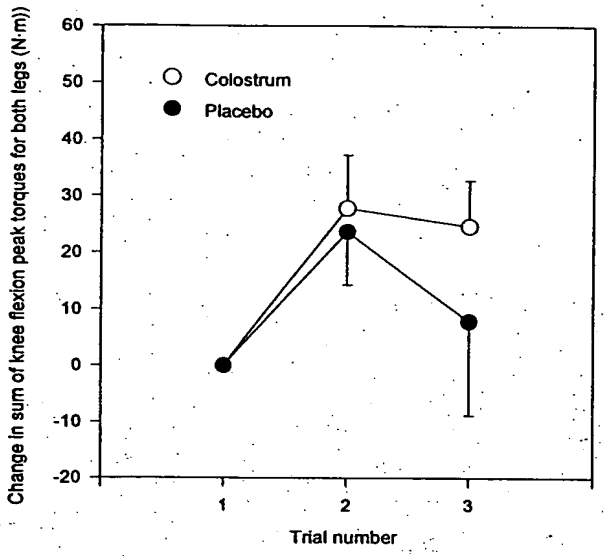

Figure 29. Change in sum of knee flexion peak torques

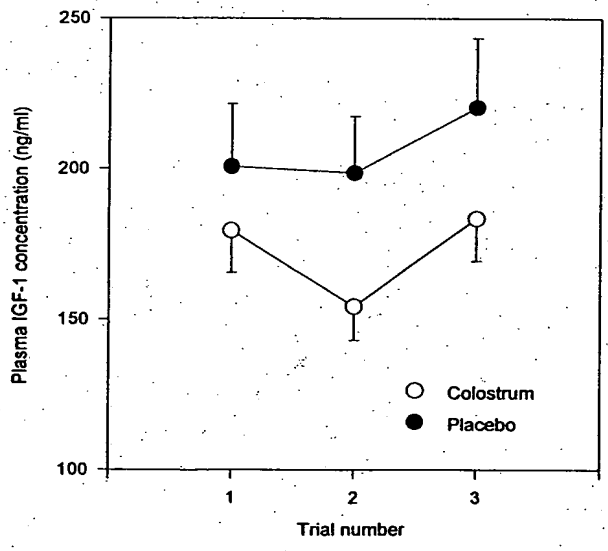

Figure 30. Plasma insulin-like growth factor 1 concentrations.

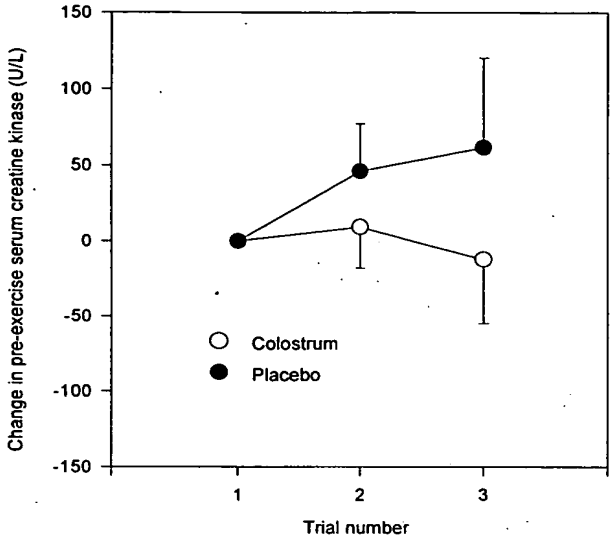

Figure 31. Change in the serum creatine kinase